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IN THE
Supreme Court of the United States
OCTOBER TERM, 1978

No. **78-1118**

PETER H. FORSHAM, ET AL.,
Plaintiff-Petitioners,

v.

JOSEPH A. CALIFANO, JR., ET AL.,
Defendant-Respondents.

**PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT**

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Plaintiff-Petitioners respectfully request this Court to issue a writ of certiorari to the United States Court of Appeals for the District of Columbia Circuit to review its Judgment in the above-captioned case.

CITATIONS TO OPINIONS BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit is not officially reported and is set out in Appendix B. The unreported Statement of Circuit Judge Bazelon as to why he voted for rehearing is set out in Appendix A. The Order of the United States District Court for the District of Columbia granting defendants' Motion to Dismiss is set out in Appendix C.

JURISDICTION

The Judgment of the United States Court of Appeals for the District of Columbia Circuit was entered on July 11, 1978. The Petition for Rehearing and the Suggestion for Rehearing En Banc were denied on October 17, 1978. Jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) to review the decision in the United States Court of Appeals.

QUESTION PRESENTED

Whether the District Court erred in finding that records derived from scientific research financed entirely by one government agency and forming the basis for action by another government agency are not "agency records" under the Freedom of Information Act, merely because the records are not housed within the physical confines of either agency.

STATEMENT OF THE CASE

This is an action brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2, to obtain records generated in the course of a scientific study conceived, directed, and entirely funded by The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD). This appeal by the plaintiffs challenges the order of the U.S. Court of Appeals for the District of Columbia Circuit affirming the District Court's dismissal of the action on the grounds that the records sought were not agency records under FOIA.

Introduction

Petitioners are three physicians who are members of the Committee for the Care of the Diabetic (CCD), an unincorporated association of approximately 200 physicians throughout the United States involved in the daily management and treatment of patients suffering from adult-onset diabetes mellitus, a disease affecting millions of Americans. Petitioners, and substantial numbers of the CCD members they represent, are not only active medical practitioners, but also leading teachers and researchers in the area of diabetology.

The records sought by plaintiffs consist primarily of specific data generated in the course of a federally-funded scientific study known as the University Group Diabetes Program (UGDP). A collaborative effort involving twelve scientific institutions around the country, the UGDP was originally formed in 1959 following a planning grant from NIAMDD. Beginning in 1960 and continuing to 1978, the UGDP has been awarded a series of NIAMDD grants totaling approximately fifteen million dollars to study the effectiveness of oral hypoglycemic drugs in preventing the complications of diabetes mellitus.

In a monograph published in December 1970¹ the UGDP reported its conclusions based on the first eight years of the study. The principal conclusion was that the combination of diet and oral medication was no more effective than diet alone in prolonging life. Also suggested was a possible correlation between oral medication and cardiovascular mortality.

¹ "The UGDP: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes", *Diabetes*, 19:2, 747-830.

Release of the UGDP conclusions triggered an immediate and large-scale controversy among physicians and scientists. Professional conferences were convened, articles were published and scientific studies, albeit of a more limited scope, were undertaken with the hope of evaluating the UGDP conclusions and determining their validity. Rather quickly, the dialogue turned into a debate with the medical and scientific communities dividing sharply along pro- and anti-UGDP lines. Supporters of the UGDP pointed to the study's cost, duration, broad patient base, and sophisticated design, as confirming the validity of the findings.² UGDP critics, on the other hand, cited numerous inadequacies in study design, methodology, and execution, not the least of which was an apparent breakdown in initial randomization which had led to a far greater predisposition to cardiovascular risk in hypoglycemic-treated subjects than in control group subjects.³

The scientific debate took on an added dimension when a UGDP investigator resigned from the study and challenged the integrity of the study's data base (Rec-

² For example:

Cornfield, The University Group Diabetes Program: A further statistical analysis of the mortality findings, *JAMA* 217:1676-1687, 1971.

Prout, Knatterud, Meinert, et al., The UGDP Controversy: Clinical trials versus clinical impressions. *Diabetes* 21:1035-1040, 1972.

³ For example:

Feinstein, Clinical Biostatistics: VIII. An analytical appraisal of the University Group Diabetes Program (UGDP) study. *Clin. Pharmacol.* 12:167-191, 1971.

Schor, The University Group Diabetes Program: A statistician looks at the mortality results. *JAMA* 217:1671-1695, 1971.

ord page 6, Exhibit A).⁴ The data in question (hereinafter raw data) were the results of the various tests administered to UGDP subjects at the beginning of the study and on a quarterly basis thereafter to assess the relative efficacies of the treatments under investi-

⁴ This UGDP investigator, Angela Bowen, M.D., testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs on August 20, 1975:

An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators.

gation. Recorded onto standardized forms, copies of the raw data had been periodically forwarded from each clinical center to the UGDP Coordinating Center at the University of Maryland where they were collected, coded, punched, and stored on magnetic discs to allow for rapid computer access and analysis. Since all data analysis was conducted at the Center under the direction of respondent Christian R. Klimt, and since all UGDP reports, including the 1970 monograph, were prepared at the Center, a challenge to the raw data was a challenge of the entire validity of the study as reported.

Even before the publication of the UGDP conclusions, the Food and Drug Administration (FDA) began issuing press releases and circulating Drug Information Bulletins to physicians around the country with the agency's revised position on the proper treatment of diabetics based on the UGDP. CCD was organized immediately thereafter in an effort to assure that both the patients who suffered from diabetes mellitus and the physicians who treated it were provided with full, accurate, and truthful information concerning the safety and efficacy of the various treatment modalities. CCD became concerned that such premature FDA recommendations would create anxiety for diabetics and confusion for their physicians. In a telegram to the FDA entitled a "Statement on the Treatment of Diabetes" (Record page 1, Exhibit S), CCD deplored the fact that physicians had been provided ~~no~~ basis for making their own assessment of the validity of the UGDP and requested that:

before any further action is taken by regulatory agencies, the [UGDP] raw data should be made available to the scientific community at large.

In a subsequent exchange of correspondence with the FDA, CCD renewed its request for an independent review of the raw data, while the FDA endorsed the UGDP based on an allegedly "full and careful evaluation" of this study's conclusions (Record page 1, Complaint ¶ 12). When shortly thereafter the FDA proposed relabeling of all oral hypoglycemic drugs to reflect UGDP conclusions, CCD petitioned the FDA to rescind its proposal and to withhold further action pending independent corroboration of the study. In its petition, CCD presented a detailed critique of UGDP conclusions and again requested access to the raw data both for itself and other qualified researchers.

The FDA denied CCD's petition on June 5, 1972, and again endorsed the reliability of the UGDP. However, in response to CCD's request for access to the raw data, the FDA responded as follows:

Your petition states that the results of the UGDP study are not available and therefore not subject to the usual critical review. *We have been assured that the UGDP personnel will honor any reasonable request for data and information.* (Record page 1, Complaint, ¶ 12) (Emphasis supplied).

However, UGDP personnel were not responsive to requests for access to the raw data, even from investigators associated with the UGDP (Record page 6, Exhibit A). Consequently, when the FDA re-initiated its attempts to require relabeling of oral hypoglycemic drugs based solely on the UGDP, CCD brought an action in the United States District Court for the District of Massachusetts to enjoin such relabeling and to require production of the raw data. *Bradley v. Richardson*, No. 72-2517-M (D. Mass., 1972).

A preliminary injunction issued enjoining the proposed relabeling, from which order the FDA appealed. In its opinion on July 31, 1973, the First Circuit Court of Appeals remanded the labeling question to the FDA while expressing in *dicta* CCD's entitlement to the raw data as being part of the administrative record. *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973). However, the FDA deferred further action on the labeling pending a report from the Committee of the Biometric Society which had been reviewing the scientific quality of the UGDP at NIAMDD request. Under its charge from NIAMDD, the Biometric Committee had been:

urged to utilize all the resources it needs to arrive at a satisfactory answer, and to prepare a report for publication Although no prior approval by the NIH is required, we shall expect to be kept informed of the conclusions as they develop. (Letter from Robert Q. Marston, Director of NIH, to Colin White, Committee Chairman, June 9, 1972, quoted in "Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents", *Journal of the American Medical Association*, 131 JAMA 615, February, 1975 (hereinafter Biometric Report)).

The fact that the Committee did not issue its final report until two and one-half years after its original charge contributed to rumors of sharp division among its members along familiar pro- and anti-UGDP lines. CCD was informed that the Committee had actually prepared an earlier draft of its report which NIAMDD had opposed due to its criticism of the Institute-sponsored study. The final Biometric Report, as published, endorsed many of the arguments on both sides of the controversy and concluded with "moderately strong" support for the UGDP. *Id.*, at 655.

Particularly relevant for purposes of FOIA is that pursuant to contract with NIAMDD, the Biometric Committee was afforded access to the raw data in the course of preparing its report. To be sure, such access was limited, since the data pertained to only one of the oral hypoglycemics studied and even then only up to October 1969 (two Committee-imposed limitations which may themselves have diminished the ultimate value of the report). Nonetheless, the UGDP raw data had been made at least partially available to persons outside of the UGDP and as a result of a government contract.

After the December, 1975 announcement by FDA of their intention to audit the raw data, a long period of official silence was maintained as to the status of the audit. During the oral argument in this FOIA action before the Court of Appeals in December 1976, government attorneys promised that all raw data which would come into FDA hands during the audit would be released under FOIA. However, despite unofficial indications that the data review phase of the audit had been completed, no data was forthcoming to the public.

On July 25, 1977, Health, Education, and Welfare (HEW) Secretary Califano suspended phenformin hydrochloride, an oral diabetes medication, as an "imminent hazard to public health" pursuant to 21 U.S.C. § 355(e). In his Order suspending the drug, Secretary Califano stated that he placed a primary reliance on the UGDP data in his decision and on the FDA's endorsement of the study.⁵

The full administrative hearing on the drug withdrawal issue which followed the suspension of phen-

⁵ Order of Secretary Califano Suspending Phenformin, at pp. 38, 40-41.

formin hydrochloride reached the oral testimony phase on October 4, 1977. Prior to the first day of testimony, all participants at the hearing, including FDA, submitted a signed statement required by regulation (21 C.F.R. § 12.85) that all documents and data in their files relevant to the case and upon which they relied had been submitted. FDA submitted no UGDP data or audit findings—only a copy of the published UGDP reports.

The CCD physicians, participants at the phenformin hearing, filed objections to the presiding Administrative Law Judge based on the FDA omission of the UGDP data. On October 6, 1977, the Administrative Law Judge ordered FDA to come forward with whatever UGDP data was in their possession. On October 7, 1977, the final day of the phenformin hearing, FDA presented the participants with several thousand pages of data gained through the FDA audit of the UGDP. These materials did not represent all raw data the FDA personnel had viewed at the coordinating center, but rather those parts of the raw data that were transcribed on FDA forms and carried back to FDA offices or directly transferred to government premises through a computer link-up. FDA attorneys stated on October 6, 1977 that the FDA audit findings, based on the submitted raw data, were in final draft stage but were not ready for submission.

After several months of informal efforts to gain public access to the audit report, CCD, on July 10th, 1978, made a renewed formal request for the report through FOIA. This request was denied on August 6th, 1978, with the statement that the report was still in draft form and was an investigative document and thereby exempt under FOIA.

On November 14, 1978, FDA published in the *Federal Register* (43 F.R. 52732) a notice of public availability of the audit report concurrently with a reissuance of proposed regulations which declared FDA's intention to relabel the oral hypoglycemic drugs—the same Federal action which CCD had challenged with the inception of the organization in 1970. In correspondence attached in an appendix to the audit report, a letter of transmittal of Fall 1977 was noted which had served to forward to the UGDP coordinating center the draft FDA audit report, which was denied to CCD as an investigative document nine months later.⁶

Controversy on the serious medical issues surrounding the UGDP has continued to date. A principal investigator at one of the UGDP clinics published results of his analysis of the UGDP data in the *Journal of the American Medical Association* on January 5, 1979.⁷ Those recent findings refuted the previously published results. The UGDP investigator performing this analysis had applied the partial data which could be made available to him from the UGDP clinics. The UGDP coordinating center had denied him access to the complete records, containing all the raw data, kept in a bank vault in Maryland.

Lower Court Proceedings

On September 30, 1975, plaintiffs filed a complaint under FOIA seeking production of the UGDP raw data and the draft Biometric Report. The complaint also sought a declaratory judgment that the withholding of the requested records both by the federal defend-

⁶ The FDA audit report contained no new unreleased UGDP data.

⁷ Kilo, Letter to the Editor, *JAMA* 241:26 (1979).

ants and by defendant Klimt was unlawful (Record page 1, Complaint ¶¶ 1, 2).

On November 21, 1975, the federal defendants moved to dismiss and/or for summary judgment. Despite the fact that fully five years earlier a regulatory action had been taken by the federal government ostensibly based on the UGDP data, accompanying federal defendants pleadings were the affidavits of the Assistant Secretary for Health for HEW and the Director of NIAMDD stating that no officer or employee within HEW or its subagencies ever had or saw the raw data and that in their judgment such data were not agency records under the provisions of FOIA (Record page 4, Exhibits 1 and 3).

On February 5, 1976, the Court dismissed plaintiffs' complaint for FOIA relief against the federal defendants and granted federal defendants' motion to dismiss.

On February 25, 1976, petitioners filed a Notice of Appeal of the District Court decision with the U.S. Court of Appeals for the District of Columbia Circuit. The case was argued before Circuit Judges Bazelon, Leventhal and MacKinnon on December 6, 1976.

Judge Leventhal, in the Opinion of the Court issued July 11, 1978, declared as the governing principle that only if a federal agency has created or obtained a record in the course of doing its work is there an agency record that can be determined under FOIA.* Further interpreting this newly announced standard, Judge Leventhal stated:

Where records are created by a private entity, we believe the applicability of FOIA will turn on

* Opinion of the Court, at p. 16.

whether the government is involved in the core planning or execution of the program, or whether, by contrast, the entity retains its private character in bona fide fashion during the course of the endeavor that results in the records. (Opinion of the Court, at 16, fn. 19)

The dissenting opinion of Judge Bazelon stated that the UGDP data were agency records for the purposes of FOIA. He cited the federal government funding of the UGDP, access to the raw data and reliance on the raw data as proof of the significant government involvement with the records required to make them agency records.

Petitioners filed a Motion for Rehearing and Suggestion for Rehearing En Banc, citing the extensive government involvement in the core planning and execution of the UGDP study which qualified the UGDP raw data as agency records under the rule announced in the majority opinion. Among the factors raised by petitioners to meet this new agency records test were the following: (1) the two year NIH planning grant which initiated the UGDP study and resulted in the creation of the plan for research; (2) the unusual degree of federal input into the ongoing study (This included a special UGDP Policy Advisory Board headed by an employee of NIH which took initiatives in directing the course of the study.); (3) the exercise of federal audit powers twice during the study; and (4) the primary mission of the UGDP Coordinating Center to coordinate grant research. The center coordinated three other major federal grants which created a continuing multi-million dollar federal commitment to the center's computer data storage and retrieval systems.

The petitions for rehearing were denied on October 17, 1978. Judge Bazelon voted for rehearing noting that

Plaintiffs make a strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive. (Statement for Rehearing, p. 2)

Further, Judge Bazelon noted in reviewing the course of the litigation,

Plaintiffs could not previously have known precisely what showing was required under the majority's novel criteria for determining whether the data were agency records. *Id.*

Petitioners request that this Court accept jurisdiction to resolve the legal issues presented herein, and, if necessary, guide the lower courts' consideration of this case on remand.

Reasons for Granting the Writ

This petition raises important questions concerning the administration of the Federal Freedom of Information Act (FOIA), 5 U.S.C. § 552. These questions concern the definition and character of "agency records" under FOIA. The particular issue involved has not been considered by this Court.

The legal issues described herein arise within a factual setting with the very broadest implications for millions of diabetic patients. Whether the UGDP Coordinating Center's published results are truly consistent with the data collected is a question with critical ramifications for diabetic patients. Diabetes mellitus is a progressive degenerative disease which dictates that treatment for the condition is a continual daily battle to combat its effects. The published UGDP find-

ings have been and continue to be the subject of federal regulatory action and policy requiring changes in the diabetic patient's treatment regime. Some of these federal positions are based *solely* on the UGDP. The risk of a misapplication of the study's data is a generation or more of diabetic patients receiving improper treatment—an irreversible tragedy which could be prevented by a full analysis of the data.

I. THE RAW DATA ARE AGENCY RECORDS BECAUSE THEY ARE THE PRODUCTS OF RESEARCH CONCEIVED, FUNDED AND SUPERVISED BY NIAMDD AND CARRIED OUT THROUGH ITS PARTNERSHIP RELATIONSHIP WITH THE UGDP.

A. The Products of Government Funded Projects Are Not the Exclusive Preserve of the Individual Producing Them and Are Therefore Not His Property.

The concept of "property" involves rights which one can exert to the exclusion of others, *Black's Law Dictionary* 1382 (Rev. 4th ed., 1968):

... the unrestricted and exclusive right to a thing; the right to dispose of a thing in every legal way, to possess it, to use it, and to *exclude everyone else from interfering with it.* (Emphasis supplied)

It is uncontested here that the UGDP Coordinating Center presently has "possession" and "custody" of the raw data. Mere possession and custody, however, do not translate into "property", for while they permit the Center a more immediate impact on the data they do not confer upon it exclusive authority. In fact, traditionally, the product of work performed within the scope of government duties belonged entirely to the government. As first enunciated by the Supreme

Court in *Solomons v. United States*, 137 U.S. 342, 346 (1890), the principle was as follows:

If one is employed to devise or perfect an instrument, or a means for accomplishing a prescribed result, he cannot, after successfully accomplishing the work for which he was employed, plead title thereto as against his employer.

This approach was further developed in the landmark case of *Houghton v. United States*, 23 F.2d 386 (4th Cir.), *cert. denied*, 277 U.S. 592 (1928), where a chemist employed by the Public Health Service patented a fumigant gas to which the government claimed title. The Court rejected the chemist's contention that the government had only limited property rights in the fumigant, since the invention had been the very purpose of the research for which the chemist had been hired and compensated. The Court also pointed out that considerable amounts of government resources, including research equipment and staff, had been expended on the project. Moreover, even beyond the particular financial interests of the government in the research was the inherently public nature of the entire undertaking:

The Public Health Service represents the people of the United States. Its interest is their interest. Its inventions and discoveries are made for their benefit. . . . In the case of the fumigant gas developed by the defendant while employed and paid by the government to develop it, they are interested, not only in the use which the Health Service itself may make of it, but also primarily in having it supplied to the public as freely and cheaply as possible. It is unthinkable that, where a valuable instrument in the war against disease is developed by a public agency through the use of public funds, the public servants employed in its

production should be allowed to monopolize it for private gain and levy a tribute upon the public which has paid for its production, upon merely granting a nonexclusive license for its use to the governmental department in which they are employed. Id. at 391. (Emphases supplied)

The principles of *Houghton* have been widely accepted and followed. *Sawyer v. Crowell Publishing Co.*, 142 F.2d 497 (2d Cir. 1944), *cert. denied*, 323 U.S. 735 (1944); *United States v. First Trust Co. of Saint Paul*, 251 F.2d 686 (8th Cir. 1958); *Public Affairs Associates v. Rickover*, 268 F. Supp. 444 (D.D.C. 1967).

The courts have applied *Houghton* principles to the case of government employment of independent contractors as well as employment of its own employees. In *Mine Safety Appliances Co. v. United States*, 364 F.2d 385, 391 (Ct. Cl. 1966), the Court found that a crash helmet developed at a private university out of privately funded research was so integrally related to the university's research contract with the U.S. Navy as to confer upon the government a royalty free license to use the helmet. Even though the invention was not specifically contracted for, it was held to be within the implied scope of the contract and a direct consequence of its performance. "There was a close and umbilical connection which was not, and could not be, severed."

The same rule was applied in *Technitrol, Inc. v. United States*, 440 F.2d 1362, 1372 (Ct. Cl. 1971), involving a magnetic disc storage system developed in the course of a computer research contract between the U.S. Army and the University of Pennsylvania:

The Federal Government has the right to use, royalty-free, those ideas, improvements, discoveries, and inventions—crystallized during perform-

ance of the federal contract—which have a “close and umbilical relationship” to the work and research funded by the United States.

This property right of the government to the benefits of government-sponsored research encompasses records generated in the course of research as well as the final research product. In *Jacobs v. United States*, 239 F.2d 459 (4th Cir. 1956) *cert. denied*, 77 S. Ct. 666 (1957), the Court upheld the government’s claim to preliminary records and drawings produced in the course of its contract for the development of a bombing system, citing *Houghton*. Even beyond the terms of the contract, this right was founded separately on fundamental considerations of equity:

[I]t is clear that, without regard to the contract, the government is entitled to the benefit of all knowledge gained by the contractor in the course of the research for which the government was paying him. (at 461)

Applying the foregoing principles to the question of rights to the data at issue, it is apparent that neither the UGDP investigators nor the Coordinating Center have an exclusive property right. Therefore, an analysis of the FOIA issues in this case which focuses on possession and property rights is inappropriate for this case.

B. By Virtue of the Partnership Relationship Between NIAMDD and the UGDP, the Government Has a Property Right In the Raw Data of the Study and An Unrestricted Right of Access.

In addition to the history of interaction between HEW and the UGDP Coordinating Center, the partnership relationship is evidenced by an elaborate regulatory structure.

HEW’s general policy on public access to grant research is stated as follows:

the public interest will . . . be best served if intensive advances resulting [from research grants] are made freely available to the Government, to science, to industry, and to the general public. 45 C.F.R. § 8.0.

And again:

It is the general policy of the Department that the results of Department research should be made widely, promptly, and freely available to other research workers and the public. 45 C.F.R. § 6.1.

More specifically, NIH officials are authorized access to

any books, documents, papers, and records of the grantee which (are) determined . . . pertinent to a . . . grant for the purpose of making *audit, examinations, excerpts, and transcripts*. 45 C.F.R. § 74.23(a). (Emphasis supplied)

Additionally, in cases where records located outside the agency are determined to have long-term retention value, they can be ordered physically transferred to government custody. 45 C.F.R. § 74.20(b). The government retains a permanent unrestricted license to use the products of the scientific endeavor. 45 C.F.R. § 8.1. Moreover, the public at large has its own rights of access to grantee records, which can be restricted only in specified instances. 45 C.F.R. § 74.24. The cumulative impact of these HEW regulations establishes the government’s dominion and control, and thereby access, to the UGDP data justifying petitioners’ demand for the raw data under FOIA.

II. RECORDS PRODUCED UNDER AGENCY SPONSORSHIP AND IN FULFILLMENT OF AGENCY RESPONSIBILITIES ARE AGENCY RECORDS UNDER THE FOIA IRRESPECTIVE OF THEIR PARTICULAR PHYSICAL LOCATION.

It is well established that records need not be prepared within the physical confines of an agency to be agency records under the FOIA. *Washington Research Project, Inc. v. DHEW*, 164 U.S. App. D.C. 169, 504 F.2d 238 (D.C. Cir. 1974), *cert. denied*, 95 S. Ct. 1951 (site visit reports prepared by outside consultants appointed to assist NIH in making grant determinations are agency records); *Wu v. National Endowment for Humanities*, 460 F.2d 1030 (5th Cir. 1972) (memoranda and other work products prepared by outside consultant to recommend course of agency action on grant application are agency records).

Further, once a document is generated by or on behalf of an agency, it does not lose its identity as an agency record merely because it ceases to reside within the agency's physical confines. In *EPA v. Mink*, 410 U.S. 73 (1973), plaintiffs sought access to reports prepared by the EPA which had been forwarded to the President's office. While custody of the materials was in the President, this did not divest them of their status as EPA records under the FOIA. Similarly, in *Soucie v. David*, 145 U.S. App. D.C. 144, 448 F.2d 1067 (D.C. Cir. 1971), records prepared by the Office of Science and Technology were held to be agency records even though no longer located within the agency.

The issue of agency records was examined in detail in *Nixon v. Sampson*, 389 F. Supp. 107, 147 (D.D.C. 1975), where plaintiff Nixon contended that materials generated by him and then currently located in the White House Office were not agency records under the

FOIA. The court acknowledged that the situs of the records was not in an agency but held that since the records were generated under the auspices of an agency, the Executive Office of the President, they remained agency records irrespective of location. As the court stated, the housing of records beyond agency confines

does not mean that [they] are immune from access under the FOIA. . . . Therefore, the FOIA plaintiffs are entitled to a declaration that they are "records" within the meaning of the FOIA. (citations omitted).

The public interest in scientific endeavor was acknowledged by the Court in *Washington Research Project, supra*, where a variety of grant-related materials pertaining to HEW-sponsored research were held to be subject to FOIA disclosure due to their factual and investigative nature. The court was well aware that particular scientists may have "a preference for or an interest in nondisclosure", *Id.* at 245, but ruled that to restrict such materials from public access was antithetical to the mandate of the FOIA as well as to the "philosophical values of science", *Id.* at 244.

The HEW response to *Washington Research Project* has particular relevance here, since it has confirmed beyond question the availability of the records requested. Prior to the decision, HEW regulations listed "raw research data" among grant-related materials "generally not available" under the FOIA. However, that restriction was removed by HEW when it amended its FOIA regulations to bring Department policy into conformance with the law of the case (40 F.R. 18997, May 1, 1975). There remain, therefore, no lawful restrictions on petitioners' rights of ac-

cess under applicable agency regulations; and under traditional FOIA principles, information not explicitly exempt must be publicly disclosed.

While demonstration of need is not required under the FOIA, the interest in disclosure of scientific data has been enunciated clearly:

The public's need for information is especially great in the field of science and technology, for the growth of specialized scientific knowledge threatens to outstrip our collective ability to control its effects on our lives. *Soucie v. David*, 145 U.S. App. D.C. 144, 448 F.2d 1067, 1080 (D.C. Cir. 1971)

In a case recently decided in the Federal District Court for the District of Columbia, *Public Citizen Health Research Group v. Department of Health, Education, and Welfare et al.*, 449 F. Supp. 937 (D.D.C. 1978), the records of a Professional Standards Review Organization (PSRO) were ordered subject to FOIA requests. PSROs monitor the medical profession and collect information on physicians and patients. This case is important for its refusal to limit the reach of FOIA where scientific, medical records, often of a sensitive, personal nature, are involved. The Court referred objections on the nature of the documents to the protections afforded by the FOIA exceptions. The basic applicability of FOIA is not to be affected.

After ruling that the PSRO records were agency records, the Court, in *Public Citizen Health Research Group* stated

While HEW has neither possession nor control of the records sought, its administrative process for processing the request can and perhaps should be used . . . (At 941)

Thus, as in the case at bar, a federal agency is required to retrieve records from outside the agency for FOIA disclosure.

III. THE RAW DATA ARE "AGENCY RECORDS" BECAUSE THEY ARE SUBJECT TO ACCESS BY THE FDA FOR AUDIT AND OTHER PURPOSES AND ARE THE BASIS FOR AGENCY ACTION.

A. FDA Has Access and Control Over the UGDP Data Through Its IND Regulations.

During the course of the UGDP controversy, CCD's efforts to obtain access to the raw data have met first with evasive, then with technical, and then increasingly negative responses from the FDA. The Agency's original position was to encourage CCD's independent examination of the raw data in the candid recognition that UGDP results could not be subjected to the usual critical review. The FDA assured CCD

that the UGDP personnel will honor any reasonable request for data and information (Record page 1, Complaint ¶ 12).

However, as the controversy developed and the UGDP Coordinating Center did not honor requests for data even from its own principal investigators,⁹ plaintiffs again requested the data under FOIA. The agency response was simply to channel the matter to NIAMDD. No longer was the Agency acknowledg-

⁹ As reported by Dr. Bowen:

. . . My co-investigator requested from the coordinating center a printout of the data from our clinic to determine whether it agreed with our own data kept in the clinic. That request, like all other requests, was refused. The jealousy with which access to the data has been guarded to all who have requested it is not reassuring (Record page 6, Exhibit A).

ing its own role relative to a study which it had adopted and on which it was basing regulatory action.

A different agency position was articulated in the Agency's final denial of petitioners' request for access to the raw data. In this communication (Record page 1, Exhibit Q), the Agency claimed that it had no *authority* to order production of such data, and that the FDA's proposal to relabel oral drugs was based solely on the UGDP report as distinguished from the underlying data.

For the FDA to deny its authority over the data is to overlook the plain meaning of its regulations relative to investigational new drugs (IND's). These regulations fully authorize the "inspection and copying" of investigators' clinical records simply upon FDA request. 21 C.F.R. § 312.1. Since the UGDP holds two IND approvals from the FDA, (Record page 1, Exhibit U), UGDP data are directly subject to the right of the Agency to inspection and copying.

The attenuated nature of the FDA position here is illustrated by its own FOIA regulation *requiring* the disclosure of raw scientific data to the public in the case of FDA-sponsored research.

Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed. 21 C.F.R. § 20.105(d).

The FDA regulations hold the products of extramural research are "agency records" in the same manner as that of intramural research.

In short, the data sought by plaintiffs would fall squarely within the scope of FOIA had the UGDP been funded by FDA rather than by NIAMDD. It

defies common sense as well as the broad purposes of FOIA to permit the end result to be determined by which of HEW's operating agencies actually funded the study, particularly where the agency whose procedures would have mandated production of the raw data is the agency placing reliance on the data to support a broad range of regulatory policies.

B. FDA Reliance On the UGDP Raw Data. Combined With Its Control Of and Access to the Raw Data Require Release Of the Raw Data Under FOIA.

As noted by Judge Bazelon in his dissenting opinion in this case, UGDP raw data have been "absorbed into the federal decision making process." (At 16, fn. 21) FOIA was designed to give the public access to this kind of data which underlies government processes.

However, the Concurring Opinion, at page 2, states that no public harm will result from the denial of public access to UGDP data in view of possible availability of subpoena authority in this matter. The shortcomings of this suggested alternative and the further litigation it contemplates reinforces the importance of FOIA access in this case. The situation with phenformin is illustrative. On July 25, 1977, the Secretary of Health, Education, and Welfare declared phenformin an imminent hazard and summarily banned it from general use without prior hearing or disclosure of any of the raw data on which the Order was based. This order was carried throughout the medical and lay press and caused confusion and alarm for thousands of diabetic patients and their physicians. While this Order was challenged by petitioners and others in concurrent administrative and judicial proceedings, these challenges are still pending at the present time,

and no final decisions have been rendered.¹⁰ After nearly 16 months since all diabetic patients were required to be removed from phenformin largely on the basis of the UGDP, no forum, administrative or judicial, has determined the merits of petitioners' challenge to the Order or petitioners' right to the UGDP raw data. Thus while after-the-fact litigation may theoretically be an alternative way of securing access to the data, it lacks the timeliness and expeditiousness of an FOI request as well as the capacity to prevent needless confusion, alarm and changes in treatment among diabetics and their physicians.

Perhaps the best explanation of this principle has been made by HEW in another context. Secretary of HEW, Joseph Califano, on March 17, 1978 in testimony submitted to the Subcommittee on Health and Scientific Research of the Senate Human Resources Committee, discussed the HEW proposal to require public access to research data generated by private drug companies. He stated:

We support the release [of this data] because we believe that FDA's decision making will benefit from the comments of scientists, representatives of patient organizations, and other interested members of the public. We also believe that disclosure of the basis for FDA's decisions will increase the credibility of those decisions with the Congress, the scientific community, and the public. Disclosure will probably lead to some increase in controversy over particular decisions, but in the

¹⁰ In *Forsham et. al v. Califano*, No. 77-1478 (U.S. District Court for the District of Columbia) and Nos. 77-2072 and 78-2288 (U.S. Court of Appeals for the District of Columbia Circuit), petitioners and other concerned physicians and diabetic patients are contesting FDA actions concerning phenformin which rely on the UGDP data.

long run we believe that controversy over FDA decisions will decrease as the basis for those decisions becomes better and more widely understood.¹¹

Additionally, Secretary Califano indicated that the duplicative testing that would result from a failure to release important drug data would "potentially expose humans to unnecessary (and therefore ethically questionable) drug testing" and "waste scarce scientific resources."¹² Therefore in the situation of privately funded research for a commercial purpose in which a company has a true proprietary interest, HEW would favor statutory public access. However, in this case, with 100% federal funding, an avowed public purpose, non-replicable research data, government reliance and a network of regulations which grant authority for release of the data, HEW has chosen a converse policy to that of public disclosure. Such inconsistency is neither appropriate nor in the public interest.

¹¹ Proposed Drug Regulation Reform Act of 1978: Hearings on S.2755 Before the Subcommittee on Health and Scientific Research of the Senate Human Resources Committee, 95th Congress, 2nd Session (Statement of Joseph Califano), at p. 16.

¹² *Id.*, at p. 14.

CONCLUSION

For the reasons set forth above, the petition for writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A

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United States Court of Appeals**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

No. 76-1308

PETER H. FORSHAM, et al., APPELLANTS

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of
Health, Education and Welfare, et al.

On Petition for Rehearing

Filed October 17, 1978Before: BAZELON, LEVENTHAL and MACKINNON, *Circuit
Judges***ORDER**

Upon consideration of appellants' petition for rehearing, it is

ORDERED, by the Court, that the aforesaid petition for rehearing is denied.

Per Curiam

Circuit Judge Bazelon voted to grant rehearing for the reasons set forth in the attached statement.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Statement of BAZELON, Circuit Judge, as to why he voted for rehearing: In their petition for rehearing, the physicians who requested the UGDP data point out the unusual degree of federal involvement in the initiation and conduct of the UGDP study, which, even under the approach taken by the majority, would bring these data within the scope of "agency records." Specifically, plaintiffs suggest that rather than an independently conceived project by scientists who "developed their own methodology," see Maj. op. at 20, the UGDP study was in fact initiated by NIH, which was responsible for developing the research protocol. Petition for Rehearing at 4. Moreover, as a condition of the renewal of the UGDP grant, NIH established a Policy Advisory Board, which, according to plaintiffs, "took initiatives in directing the course of the [UGDP] study," further evidence of government involvement in the on-going UGDP research. *Id.* at 3-4.

The majority opinion notes that "where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program." Majority op. at 16. Plaintiffs make a strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive.

Thus, in addition to the reasons set forth in my dissenting opinion, plaintiffs' contentions might well furnish an additional basis for finding these data to be "agency records." Plaintiffs could not previously have known precisely what showing was required under the majority's novel criteria for determining whether the data were agency records.¹ They have now raised a significant

¹ According to the majority, government involvement in the "core" of a program, see Maj. op. at 16 n.19, 21 is the key to determining whether records created by private individuals or groups are "agency records", which appears to be the first use of that concept in connection with the definition of agency

factual question which, under the majority's approach, warrants a remand to determine the degree of NIH involvement in the initiation and conduct of the UGDP study, rather than an affirmance of the district court, which had focused exclusively on the physical possession and ownership of records.²

records under FOIA. *Cf. Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977) where the district court, considering another FOIA request for the UGDP data noted that "[t]here is little official authority to aid the Court in discerning whether documents are agency records." *Id.* at 529. It is noteworthy that the principal authority which "lighted" the majority's path was not even a FOIA case, but an action under the Federal Tort Claims Act. See Maj. op. at 12-13, discussing *United States v. Orleans*, 425 U.S. 807 (1976).

² Admittedly, the contentions raised in the petition for rehearing are somewhat conclusory. If, however, the plaintiffs lack factual support sufficient to show government involvement in the core of the program, the district court will then be justified in dismissing the suit.

A far less satisfactory course would be to permit plaintiffs to elaborate their contentions on rehearing in this court. Such supplementation would not consist of adducing evidence, but would more closely resemble a proffer, designed to permit us to assess whether a remand in lieu of affirmance would be any more than a formal gesture. I believe that this approach is inferior to directly remanding this case to the district court because the questions involved are largely factual, and to explore them here may work substantial prejudice to both sides by denying them the opportunity to develop the relevant facts through further investigation, discovery and stipulation in the district court. Only with such a record can a court adequately judge the degree of NIH's involvement in the "core" of the UGDP study. However, I do not believe that we should cut off all avenues for the plaintiffs to show the requisite degree of government involvement in initiating and directing the UGDP study, and therefore I voted for rehearing.

APPENDIX B

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United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., APPELLANTS

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of Health, Education and Welfare, et al.

Appeal from the United States District Court
for the District of Columbia

(D.C. Civil 75-1608)

Argued December 2, 1976

Decided July 11, 1978

Harvey W. Freishtat, with whom Anthony J. Rocco-grandì was on the brief, for appellants.

Michael Kimmel, Attorney, Department of Justice, with whom Rex E. Lee, Assistant Attorney General, Earl J.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Silbert, United States Attorney and Leonard Schaitman, Attorney, Department of Justice, were on the brief, for Federal appellees.

Mary Elizabeth Kurz, Assistant Attorney General of the State of Maryland, with whom David H. Feldman, Assistant Attorney General of the State of Maryland was on the brief, for appellee, Klimt.

Before: BAZELON, LEVENTHAL and MACKINNON, Circuit Judges.

Opinion for the Court filed by Circuit Judge LEVENTHAL.

Concurring opinion filed by Circuit Judge MACKINNON.

Dissenting opinion filed by Circuit Judge BAZELON.

LEVENTHAL, Circuit Judge: In its broad aspect this appeal presents the question whether and under what conditions data compiled by a private group that is receiving money under a federal grant-in-aid program are or become "agency records" by virtue of the fact that the agency has funded the program and has the authority to demand those records.

An action was brought by specialists in the treatment of diabetes, as individuals and a committee,¹ to obtain raw research data of the University Group Diabetes Program (UGDP). The program is a privately conducted and federally funded long-term clinical study of the treatment of diabetes, that has reported certain harmful consequences attendant upon the long-term use of oral hypoglycemic agents. Plaintiffs question the validity of the study, and are concerned lest a useful therapeutic tool be unnecessarily removed from the market. They

¹ Three physicians sue in their own behalf, and in behalf of the Committee on the Care of the Diabetic, described in the complaint as an unincorporated association of 178 physicians involved in the daily treatment and management of diabetes.

seek access to the raw data in order to implement their challenge to the study's validity.

The action was brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. That Act is addressed to each "agency" of the Federal Government as defined.² Broadly speaking, and subject to exceptions, it directs each agency to make available to the public certain information, and also "agency records." It establishes the District Court's "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a) (4) (B).

A. BACKGROUND

1. *The UGDP Study and the Sponsoring Institute*

The UGDP is a study funded by 13 federal grants administered by the National Institute of Arthritis, Metabolism and Digestive Diseases (hereafter sometimes Institute or NIAMDD). That institute is an "agency" under the Act, being part of the National Institutes of Health, which in turn is an organization within the Public Health Service, in the Department of Health, Education and Welfare. The grants were made under the statutory grant-in-aid authority of the Public Health Service Act, 42 U.S.C. § 241(c). The grants were made to each of 12 participating university medical centers on the basis of their applications, and a grant was made

² 5 U.S.C. § 552(e):

For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

to the UGDP Coordinating Center at the University of Maryland.³

The pertinent background facts are presented in the affidavit of Dr. G. Donald Whedon, Director of NIAMDD:

4. The inspiration for the UGDP study came from private non-government physicians and scientists in mid-1959. Between 1959 and 1961, before the study actually began with the entry of the first patients, the design, methods, and objectives of the study were evaluated by persons associated with the UGDP and representatives of NIAMDD. The Food and Drug Administration was not involved in the planning, in-

³ The institutional grantees are:

Case-Western Reserve University
Cincinnati, Ohio
Greater Baltimore Medical Center
Towson, Maryland
Jewish Hospital and Medical Center of Brooklyn
Brooklyn, New York
Virginia Mason Research Center
Seattle, Washington
Massachusetts General Hospital
Boston, Massachusetts
Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois
University of Alabama
Birmingham, Alabama
University of Cincinnati
Cincinnati, Ohio
University of Maryland
Baltimore, Maryland
University of Minnesota
Minneapolis, Minnesota
University of Puerto Rico
San Juan, Puerto Rico
Washington University of St. Louis
St. Louis, Missouri
West Virginia University
Morgantown, West Virginia

ception, or design of the UGDP study. The study was funded by NIAMDD as part of its responsibility to support research in the field of diabetes and not with any specific regulatory objective in mind.

* * * * *

9. The UGDP raw data (e.g., patient charts and forms) are the property of the individual investigators and the Coordinating Center and are not owned by NIAMDD. Furthermore, it is not the normal practice of NIH or this Institute to require grantees to submit their raw data for review and, in fact, submission of raw data to the institute is extremely rare. Management of the day-to-day operations of grant-supported activities is the responsibility of the grantee. Supervision of the grantee's funded activities by this Institute is generally limited to review of periodic reports submitted by the grantee. (45 CFR §§ 74.80, 74.82). Due to the large number of research grants outstanding—currently approximately 1800—it would not be physically possible for the Institute to subject raw data, if submitted, to critical review, and to require submission of the raw data of the UGDP study would have been an extraordinary requirement. It is the practice to evaluate applications for renewal grants on the basis of progress reports and final reports submitted to NIH. This practice was followed with respect to the UGDP grants. No specific provisions of the UGDP grants required submission of raw data to the Department of Health, Education and Welfare. Pursuant to 45 CFR § 74.23, officers or employees of the Department could obtain access to the raw data for purposes of audit inspection and copying if access is deemed pertinent to the grant. The raw data which are the subject of this case have never been seen by, or been in the possession of, any officer or employee of the National Institutes of Health. * * *

The particular documents sought by the plaintiffs in this case are observations on over 1000 diabetic patients,

who were monitored from 5 to 8 years. It is estimated that there are some 55 million such documents.

In June, 1970, the UGDP investigators made a presentation of the methods and initial results of their study at the annual meeting of the American Diabetes Association. The results indicated that the administration of tolbutamide (an oral hypoglycemic drug) to mild adult-onset diabetics led to a death rate from cardiovascular disease higher than that of groups treated with diet alone, with a fixed dosage of insulin, or with a variable dosage of insulin. The findings were published in the December 1970 Journal of the American Diabetes Association. During 1970 and 1971, over a dozen articles were published in medical journals concerning the study, some supportive and some critical.⁴

The NIAMDD contracted in 1972 with the Biometric Society, a private international professional society of biostatisticians, for an in-depth assessment of the quality of the UGDP study. The Society made a report to the Institute in 1974 that apparently found some merit on both sides of the controversy. It concluded that while some of the criticisms of the UGDP study were valid most were unpersuasive, and the evidence of harmfulness adduced in the UGDP study was "moderately strong." This was made public in the American Medical Association Journal for February 1975.⁵

2. Food and Drug Administration

The Food and Drug Administration of HEW, on being apprised of the UGDP results, issued in its October, 1970, Bulletin to the medical community a recommendation that tolbutamide should be used only in cases of adult-onset,

⁴ For a listing see 40 Fed. Reg. at 28592.

⁵ 131 AMAJ 615.

stable diabetes that could not be controlled by diet and could not be treated with insulin. A June, 1971, FDA bulletin proposed changes in labeling of oral hypoglycemic drugs to warn of cardiovascular hazards. Plaintiff committee sued to enjoin the proposed labeling on ground of deficiencies in the UGDP study, and the First Circuit remanded to the FDA for exhaustion of administrative remedies.⁶

The FDA deferred further action on the labeling pending the review of the UGDP study by the Biometric Society. As already noted, the 1974 report of the Biometric Society was mixed, but overall found "moderately strong" evidence of harmfulness in the UGDP study. Its contract with NIAMDD did not require the Society to seek access to the UGDP raw data, but it apparently did examine some of the raw data.⁷ The contract did not require the Society to submit any raw data to the Institute, and none was submitted.

⁶ Bradley v. Weinberger, 483 F.2d 410 (1st Cir. 1973). Plaintiffs contended *inter alia* that prior to regulatory action, the UGDP raw data should be made available to the scientific community. In reversing a preliminary injunction restraining the proposed relabeling, the First Circuit remanded to the FDA, ruling that the underlying questions required review on the full administrative record. Judge Coffin's opinion takes note (p. 414, fn.4) of plaintiffs' contention that the record must include, *inter alia*, the original patient records of the UGDP study, and continues: "While in light of our discussion we need not resolve the propriety of each of these requests, we reiterate what we recently said in an analogous situation: 'We think the law requires production of the entire administrative record . . . where the correctness of factual findings are [sic] involved. . . .'"

⁷ Plaintiffs say this access was impaired by Society-imposed limitations: to data for only one of the hypoglycemics studied, and only the period prior to October 1969.

3. FOIA requests and District Court proceedings

Stressing that the raw data had been made available to the Biometric Society, plaintiffs' committee began a series of FOIA requests in 1974 and 1975 for access to the raw data and a copy of the draft report of the Biometric Society. Plaintiffs were given preliminary galley proofs of the report later published in the AMAJ. HEW notified plaintiffs on August 7, 1975, that the raw data were the property of those engaged in the UGDP study and had not been reviewed or even seen by either the UGDP sponsor (NIAMDD) or FDA.

This FOIA action was begun on September 30, 1975. The complaint sought the production of the raw data, defined as consisting of the forms transmitted to the Coordinating Center and the computer tapes and/or programs on the basis of which the data were analyzed. The complaint also sought a draft report of the Biometric Society.⁸

On Feb. 5, 1976, the district court granted the motion of the HEW officials to dismiss the complaint, on the ground that no official or employee of HEW is now or has ever been in possession of the raw data relating to UGDP, that these raw data are the property of the individual investigators and UGDP study coordinating center, and in the Center's possession, custody and control; that neither the investigators nor the Coordinating Center is an "agency" within 5 U.S.C. § 552, and that the raw data are not "agency records" subject to the disclosure provisions of FOIA.⁹

⁸ It is not clear what draft report is intended, other than the galley proofs already supplied of the subsequently published in February, 1975, see fn.5, above.

⁹ The district court dismissed as moot a motion by defendant Dr. Klimt, the director of the UGDP Coordinating Center at the University of Maryland, to quash service of process. Dr.

4. *Developments pending appeal*

On July 25, 1977, while the appeal to this court was pending, Secretary of HEW Califano issued an imminent hazard order suspending new drug applications for phenformin (another oral hypoglycemic drug), and there ensued administrative withdrawal hearings. This court requested supplemental memoranda of the parties on the question of whether data that would become available to plaintiffs as a result of these administrative proceedings would moot the present controversy. The federal appellees put it that there is neither certainty nor likelihood that plaintiffs will obtain access to all the data they seek as a result of the phenformin proceeding. They note, for one thing, that phenformin was only one of the oral hypoglycemic drugs subject to the warning of the UGDP study, the principal one being tolbutamide.

However, it appears that the FDA did examine certain of the underlying raw data (a small portion, quantitatively) in the course of a recent limited audit of the UGDP, and that this portion of the underlying information (except patient-identifying information) has been made available to plaintiff-appellants, and to other interested persons, participating in the phenformin proceeding. The federal appellees' memorandum states: "The FDA has no present intention of obtaining the remaining portions of the UGDP raw data through the auditing rights of the Secretary."

B. ANALYSIS

We rule that the public at large does not have a right under the Freedom of Information Act to the underlying

Klimt's directorship was based on his position as Director of Clinical Investigation in its School of Medicine. He was represented by the office of the Attorney General of Maryland.

raw data in the hands of the investigators and university groups who conducted the UGDP study program of diabetes under grants from the federal government.

1. The plaintiffs are a respected group of medical specialists asserting that their access to the data would inure to the public interest, by virtue of their concern that the use of drugs they deem valuable may be inhibited. We begin our analysis by observing that in this proceeding under the Freedom of Information Act, the court cannot give any weight to such a consideration.

The only claim ascertainable in this FOIA action is the right of any member of the public, motivated by whatever reasons. The Freedom of Information Act does not depend on a showing of need or interest by the particular applicant for the records. Any showing of need or interest is irrelevant.¹⁰ Such considerations as need, interest, or public interest may bear on the agency's determination of the order of processing applications, but they have no bearing on the substantive right under FOIA to access to the document.¹¹

¹⁰ *Sterling Drug, Inc. v. FTC*, 146 U.S.App.D.C. 237, 244, 450 F.2d 698, 705; *Robles v. EPA*, 484 F.2d 843, 847 (1973), repeating the quotation from *K. Davis, Administrative Law*, 1970 Supp. § 3A.22 (disclosure was never to "depend upon the interest or lack of interest of the party seeking disclosure").

See also K. Davis, id. at § 3A.29: "The Act never takes into account the need of the party seeking the disclosure; it never calls for balancing that need against the interest of a party adversely affected by disclosure. This policy choice reflects pressure from the press that 'the public as a whole has a right to know.'"

¹¹ It is not relevant under FOIA that the published results of the UGDP were controversial; or that, as plaintiffs allege, the government relied on these results. If the Government examined "UGDP raw data at first hand" (dissent at 10), such data have become agency records and are subject to FOIA. If the Government has relied on results of a study

2. To avoid any possible misunderstanding, we articulate that our ruling embodies no implication as to whether plaintiff physicians will have a right of access to the data underlying the UGDP study in connection with any existing or future actions of the Food and Drug Administration. That issue is distinctly different from what is before us now, and would have to be decided in the light of the record before the FDA.¹²

based on data that it has not examined, a challenge that this was arbitrary—a matter we do not here decide—may proceed by well-established mechanisms independent of FOIA.

¹² Plaintiffs' memorandum puts it that the First Circuit's opinion impliedly recognizes such a right. While a glimmer of sympathy for plaintiffs' position may be extracted from a reference in that opinion, tucked away in a discreet footnote, all that is said by the court is that the case in court must be determined on the basis of the entire administrative record. The issue here is whether the data in the hands of the researchers are part of the agency's records.

The issue of fairness to plaintiffs will require attentive consideration in the light of the administrative record. When issues of risk of harm are involved, an agency may use results of scientific researchers even without access to underlying data, as is evidenced by the frequent use of foreign studies, see e.g., *Ethyl Corp. v. EPA*, 176 U.S.App.D.C. 373, 400, 541 F.2d 1, 28 (en banc), cert. denied, 426 U.S. 841 (1976). In the present case the government has undertaken some audit review of the raw data. Plaintiffs' memorandum argues that this audit was subject to limitations that undercut its utility, but obviously we cannot appraise that issue on the record before us at this time. A court reviewing the situation on the entire administrative record would also take into account the appraisal of the Biometric Society. We cannot on our record appraise its work and its significance, let alone either plaintiffs' aspersions on the way in which that Society's committee conducted itself or the government comment that its membership embraced a wide span of scientific opinion.

The Biometric Society set forth flaws in the work of the UGDP investigators, but when an investigation requires a protracted period flaws are not wholly unexpected, and their

The FDA and NIAMDD are both in HEW, but that department is a conglomerate that embraces many and distinctly different activities. Insofar as it is engaged, through FDA, in a regulatory program, it may be subject to requirements of revelation that go beyond the FOIA's rules that govern all agencies. The FDA's regulatory actions are not before us in this FOIA lawsuit, which focuses on whether data become HEW records by virtue of study and granting activities (of NIAMDD).

3. This action requires that the persons invoking the FOIA show that they seek "agency records." The NIAMDD is a government agency, of course. But the persons or institutions who receive study grants from that Institute, or indeed from any branch of the federal government, do not on that account become government agencies.

To some extent, our path is lighted by *United States v. Orleans*, 425 U.S. 807 (1976). The case involved the Warren-Trumble council, a community action agency operating as a non-profit corporation under Ohio law, that was funded entirely by a federal agency, the Office of Economic Opportunity. Under the Economic Opportunity Act of 1964, the OEO furnished financial assistance to a community action agency, in turn defined as one designated by the state to plan and administer a community action program of "services and activities having a measurable and potentially major impact on causes of poverty in the community." The issue was whether or not one of the activities of the Ohio community action agency, the sponsoring of recreational out-

appearance may still leave the study with utility for appraisal of risk of harm to the public. See *Certified Color Manufacturers Assoc. v. Mathews*, 177 U.S.App.D.C. 137, 543 F.2d 284 (1976). The reviewing court would also consider the reasons, if any, given in any FDA proceeding involving oral hypoglycemic drugs for denying participants access to the raw data.

ings for children, if conducted negligently, could give rise to an action under the Federal Tort Claims Act. The Supreme Court held that it could not, since the council was not a federal agency or instrumentality, and its employees not federal employees. The Court found that a critical element in distinguishing a federal "agency" from either a contractor with the federal government or a grantee of the federal government, was the federal government's "control [of] the detailed physical performance." ¹³

Our decision today is congruent with our decision in *Washington Research Project v. HEW*, 164 U.S.App.D.C. 169, 504 F.2d 238 (1974), which reversed a district court order granting disclosure of certain reports made to the National Institute of Mental Health, a unit of the Public Health Service of HEW. The case involved reports made, on applications for research support, by peer review groups ("initial review groups" or IRG). The IRG peer review system was established by the government to assure competent evaluation of proposals through the use of "expertise of nongovernmental consultants functioning in panels organized around particular specialized disciplines within the broader field of biomedicine." ¹⁴

¹³ At fn. 5, 425 U.S. at 816, the Court put it that the issue was whether "there was day to day control of a program," it being irrelevant whether the program was funded by means of a contract or grant. The Court stressed (425 U.S. at 815): "Billions of dollars of federal money are spent each year on projects formed by people and institutions . . . responsible to the United States for compliance with the specifications of a contract or grant, but they are largely free to select the means of its implementation." The Court found it irrelevant that the local council did not obtain funds from any other sources or conduct any programs without federal money (425 U.S. at 818 n.7).

¹⁴ 504 F.2d at 242.

The reports sought included a "site visit" to observe the pertinent experimental technique, and a "summary statement" of the observations and deliberations of the group, prepared by a NIMH staff member assigned to assist the group. The legal issue focused on whether the initial review group was itself a government "agency," in which case its own reports would be "final opinions" required to be disclosed under FOIA, and not intra-agency memoranda excluded under exemption 5. Acknowledging the "myriad organizational arrangements for getting the business of the government done," ¹⁵ the court concluded that "the IRG's are advisory committees, performing staff functions through the medium of outside consultancy, and are not agencies." ¹⁶ It observed, significantly, "Employing consultants to improve the quality of the work that is done cannot elevate the consultants to the status of the agency for which they work unless they become the functional equivalent of the agency, making its decisions for it." ¹⁷

4. Plaintiffs seek to avoid a head-on contention that federal grantees be assimilated as federal agencies. Instead they emphasize a congeries of considerations that they think cumulate to a right of public access to documents in the hands of the grantees.

¹⁵ 504 F.2d at 246.

¹⁶ 504 F.2d at 246.

¹⁷ 504 F.2d at 248. Such consultants are employed and paid under the Public Health Service Act, 42 U.S.C. §§ 210, 217a. The court acknowledged that the consultant group's recommendations were undoubtedly "an often crucial element" in the approval process of the government, which was often typically a "perfunctory review." It regarded the degree of scrutiny as irrelevant to the court's consideration, stating that the fact that the government "may be greatly influenced by the IRG's expert view does not make the IRG an agency."

In addition to the responsibility of plaintiffs and a claim of public interest in their access, which we have already shown to be irrelevant, plaintiffs stress the following: This was a multi-million dollar study, entirely funded by the federal government, of such a scale as to be non-replicable by private efforts and a unique public resource. By contract and regulation, the raw data underlying the study are available for government review, copying and storage. The government's exercise of its rights of audit demonstrates its "complete dominion and control" over the data through the audit process.

The Institute's grant documents establish its right of access to "any books, documents, papers, and records of the grantees" for certain purposes. To the extent that the language of the grant is material, it indicates that these are not agency records prior to the exercise of that right.

Plaintiffs' claim is in effect an assertion that the federal government should be required—formally or constructively—to exercise its contract-grant right of access in order to provide general public access. We cannot accept this proposition. The Freedom of Information Act only gives a right of access to agency records in existence. It does not confer a right to have the government generate agency records, either by creation, subpoena or contract demand. That conclusion is implicit in *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975). The Court there granted the public a right to the production of the agency's appeal memorandum, pursuant to its understanding that the Act "represents a strong congressional aversion to 'secret [agency] law.'" (421 U.S. at 153). However the Court held that the public had no right to a judicial requirement that the agency produce or create explanatory material in the case of an appeals memorandum that referred only conclusorily to the "circumstances of the case." See 421 U.S. at 161:

The Act does not compel agencies to write opinions in cases in which they would not otherwise be required to do so. It only requires disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

The governing principle is that only if a federal agency has created or obtained a record (or has a duty to obtain the record)¹⁸ in the course of doing its work, is there an agency record that can be demanded under FOIA.¹⁹

¹⁸ Judge MacKinnon's opinion leads me to acknowledge that this parenthetical reference is, strictly speaking, dictum. Yet in rejecting the claim that there is an FOIA entitlement because of the *power* of the agency to obtain a record, it seems material to observe that I see a distinction where the agency has the *duty* to obtain the record. In that instance, I do not conceive that the official may lawfully resist the claim for the document on the ground that he has chosen to violate his official duty (to obtain it). In legal terms, the claim and lawsuit are in effect a joinder of two requests, and a joinder of an action in mandamus with one under the Freedom of Information Act.

¹⁹ We do not suggest that mere physical possession of records by a government agency is the sole criterion for determining whether they fall within the scope of FOIA. Obviously a government agency cannot circumvent FOIA by transferring physical possession of its records to a warehouse or like bailee.

Where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program, or whether, by contrast, the entity retains its private character in bona fide fashion during the course of the endeavor that results in the records. Even in the latter situation, however, records that are examined by the government through audit rights may become agency records under FOIA—if, for example, the records are copied by the agency or come into its possession.

5. Overarching policy considerations are stressed by physician applicants. There is a plea for liberal reading of reform legislation. We agree that this reform legislation should not be niggardly construed in contravention of legislative objective. The "basic thrust" of the Act embraces "a general philosophy of full agency disclosure" subject to specific exemptions and the objective "to pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny."²⁰

However, the general policy of avoiding agency secrecy does not give a charter for extending the law beyond the domain of "agency" and "agency records" that is the keystone of the Act. To stretch for data in the possession of federal grantees, cannot be justified as within the fair contemplation of Congress either at the time the law was passed or amended, or even today under a doctrine of trying to reconstruct specific legislative intent in the light of the broad purposes disclosed by Congress.²¹

It is tautology to say that requiring disclosure of grantee records will promote the disclosure policies of FOIA. But disclosure is not required by the statute unless those records are agency records. Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all countervailing considerations.

If the statute is to be given the kind of interpretation sought by plaintiff physicians, the impact would be

²⁰ Department of Air Force v. Rose, 425 U.S. 352, 360 (1976). Opinions of this court to the same effect include Bristol Myers Co. v. FTC, 138 U.S.App.D.C. 22, 25, 424 F.2d 935, 938 (1970); Getman v. NLRB, 146 U.S.App.D.C. 209, 211, 450 F.2d 670, 672 (1971).

²¹ Montana Power Co. v. FPC, 144 U.S.App.D.C. 263, 445 F.2d 739 (1970), cert. denied, 400 U.S. 1013 (1971).

far-reaching. The number of documents in any one study would be stupendous—reaching millions in the single case before us. The number of federal grants and contracts is not a matter of record, but as was noted in *Orleans*, they account annually for disbursements in the billions. The awesome implications of plaintiffs' contention cannot be shrugged off because modern technology permits access to documents on tape through computer printouts, without need for physical production.

Scientists engaged in research on federal grants must accept the fact that any documents filed with the federal government, whether on the scientists' own initiative or an audit or other lawful demand, are subject to FOIA. Even in scientific terms, any such audit provides a surrogate for the kind of reliability usually accorded to scientific studies by replication of experiments when feasible. However, an undertaking to be audited by responsible personnel is not the same as an agreement to accept rummaging by the world at large.

The court will not trim FOIA by speculation as to adverse motivation or reaction of the scientists.²² Similarly, the court cannot supply the extension of the reach of the Act sought by plaintiffs by building on a policy speculation that such an extension would not throttle scientific cooperation and research. This involves matters beyond our proper sphere of judicial notice.

What is requested in this action, in our view, is an extension of the statute on claim of public interest that

²² In considering Exemption 4 for trade secrets or commercial information, the court found it irrelevant to inquire whether non-commercial scientists are either "a mean-spirited lot who pursue self-interest as ruthlessly as the Barbary pirates did in their own chosen field," or are governed by the loftier consideration that "secrecy is antithetical to the philosophical values of science." *Washington Research Proj., Inc. v. HEW*, 164 U.S.App.D.C. 169, 175, 504 F.2d 238, 244 (1974).

must be appraised by the legislature which can give the subject extended study, elicit opinions from all interested sources, and consider the pro's and con's.

6. It is fitting to close by referring to the need, in any pondering of such extension of the FOIA, for considering the impact on the philosophy and purpose of Federal grant programs.

Grant programs represent a means for the governance of our society which is rooted in a pluralistic conception of the value of drawing on both private and governmental sources. A leading student of Federal grant law puts it²³

The grant is assistance to an autonomous grantee. The grantee is not an arm, agent or instrumentality of the grantor. The employees of the grantee are not federal employees. The torts of the grantee are not federal torts. The property of the grantee is not federal property.

The reference to "an *autonomous* grantee" is a core concept, not an incidental observation. In a grant program the federal government gets the advantage of services rendered by someone who is doing his own thing, his own autonomous thing. It is not the same as a government operation in disguise.

Through its grants to university groups, the government obtains the efforts of creative persons who flourish in an academic atmosphere. Such arrangements provide a measure of detachment and independence from the mission of the government agency. The researchers may feel the tug of government purse strings, but they also feel answerable to the standards of their academic colleagues.

Plaintiffs cite the multi-million dollar nature of the study as a reason for access. There is at least a ques-

²³ M.S. Mason, *Current Trends in Federal Grant Law-Fiscal Year 1976*, 35 FED BAR 163, 167-68 (1976).

tion whether the federal government could have conducted directly, through its own employees and resources, a study program so long in time, so broad in space, and covering so many patients and controls. Even in a case where the grant is to conduct a study that might conceivably be conducted by federal employees, there is an advantage in terms of effective government and advancement of the public interest if the study is done by various institutions. The government goes beyond the capabilities of its own employees, adding the spirit and insights of the scientists and students who have selected a different life style, at a center of learning.

As earlier noted, we are not concerned here with the kind of case where the federal government exercises detailed control over operations. Such a condition presents different considerations, as noted in *Orleans*. Nor do we have a suggestion of subterfuge, with a federal agency seeking to conduct research outside the scrutiny of government laws, by using facilities that are independent only nominally. The case before us concerns a UGDP study conceived in 1959 by private, non-government physicians and scientists. They developed their own methodology; it was not dictated by the federal government.

Of course, in any program funded by the federal government there is an opportunity for the government to assess the results of the performance and of any studies. There may also be directions by the federal government in certain matters of public policy that are essentially peripheral to the core of the work done. There may, for example, be a requirement of avoidance of discrimination on grounds of race, religion, creed or sex. There may be achievement of other government objectives which apply across the board to all activities financed by the federal government.

The central question is whether the government is really involved in the core of the program. At least in a case such as the one before us, where there was no claim of significant government control of day-by-day operation, or detailed involvement in the planning or execution of the program, the overall concept of autonomy of grantees persists, even though there are federal objectives, right of federal audit and perhaps some overarching federal requirements.

At least a fleeting reference should be made to acknowledge that some of the federal grantees are institutions of the state governments.²⁴ There are thus considerations of federalism involved. These are not necessarily of constitutional dimension. However, they are not without relevance in appraising the extent to which such grantees are automatically governed by rules provided by Congress for the federal agencies, such as govern access to records and meetings, or personnel management,²⁵ or any other rules.

The foregoing matters indicate that a balance must be struck, one that considers the advantages of grantees that are autonomous and have value because they are not governmental, and the possibly conflicting policy that cherishes full and free public access to government agencies and shuns secrecy as invidious. Such a balancing is a task for the legislature. The extension of access sought by plaintiffs on the ground of public interest is not properly addressed to the courts.

Affirmed.

²⁴ See note 9, *supra*, as to University of Maryland.

²⁵ National League of Cities v. Usery, 426 U.S. 833 (1976).

MACKINNON, *Circuit Judge*, concurring: I join generally in Judge Leventhal's opinion but wish to add the following observations.

5 U.S.C. § 552(a)(3) provides: "[E]ach agency, upon any request for *records* . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a)(4)(B) also refers to the location of "*agency records*" as constituting one basis for conferring on the district court for that district "jurisdiction to enjoin the agency from withholding *agency records* and to order the production of any *agency records* improperly withheld from the complaint. In such a case the court . . . may examine the contents of such *agency records* in camera" (Emphasis added.) A fair conclusion from the foregoing indicates that it is not just "records" but "*agency records*" that the statute is addressing.

The court's opinion at page 16 states:

The governing principle is that only if a federal agency has obtained a record (*or has a duty to obtain the record*) in the course of doing its work, is there an agency record that can be demanded under FOIA. [Emphasis added.]

The italicized statement is not necessary to our decision and I do not join in it. Each particular case involving a request for records not in the possession of an agency but for which, it is alleged, there is some duty to obtain the records must be decided on its particular circumstances. I would leave to a future opinion any declaration as to the extent to which FOIA should be interpreted to cover records not created by, obtained by, or otherwise in the possession of an agency. The plain implication derived from the language of the statute is that it does apply to records which belong to the agency or are in its possession—that is, records which the agency has created or obtained. That is all that is needed to decide

this case. I would not refer to records about which it might be said that an agency might have some duty to obtain until such time as we are presented with a case that raises the question directly and presents to us all the relevant facts necessary to decide the applicability of FOIA to that situation.

The dissent would go even further and substitute for the normal interpretation of the language of the statute a meaning to be derived from an extraneous examination of "all the relevant circumstances surrounding the creation, preservation, and use of [the] particular records" (Dissent at 6, emphasis original). Then, "[i]f this analysis reveals a significant degree of federal involvement with the records, then they should be considered agency 'records' subject to FOIA" (*Id.*, footnote omitted). The *catch* is allowing the interpretation of the statute to turn upon what a judge might consider a "significant degree of federal involvement." The attempt is to impose a "chancellor's foot" standard which varies with each judge. The statute, however, is not susceptible of such construction, and happily so, for those whose foot gives them a short standard would find records to be "agency records" wherever there was any federal funding or access to the records. That standard, as applied by some courts, would extend FOIA to practically unlimited lengths in those universities and industries which engage in private research. If Congress desires the Act to be so extended, it can do so by enacting appropriate legislation; but my view coincides with that expressed in Judge Leventhal's opinion, that such an extreme extension of the Act should not be created by judicial fiat.

In reaching this conclusion, I see no harm to the public. Where particular records are the subject of legitimate inquiry, as in the two cases referred to in the dissent, they may be subpoenaed by interested parties.

BAZELON, *Circuit Judge, dissenting*: Plaintiffs seek disclosure of the raw data of a federally-sponsored research project, the University Group Diabetes Program (UGDP). The UGDP data are locked in a bank vault in Maryland in the custody of the UGDP program coordinator. For the majority, this means they are not agency "records" subject to disclosure under the Freedom of Information Act (FOIA). With all due respect, I cannot agree.

In my view, factors other than possession are relevant in determining whether the UGDP data are agency "records." The Federal Government has provided all of the funding for the UGDP; the Government has an unrestricted right of access to the data; and importantly, the Government has extensively relied on the UGDP study and data in regulatory action affecting the treatment of diabetes. I think these factors cumulatively establish a significant degree of federal involvement with the UGDP raw data. Accordingly, I would hold that they are agency "records."

I.

The Freedom of Information Act requires federal agencies to disclose all "records," 5 U.S.C. § 552(a)(3),¹ that

¹ [E]ach agency, upon request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

5 U.S.C. § 552(a)(3) (1974). As originally enacted, this section provided:

[E]ach agency, on request for identifiable records made in accordance with published rules stating the time, place, fees to the extent authorized by statute, and procedure to be followed, shall make the records promptly available to any person.

[Continued]

do not fall within one of nine exemptions. *Id.* § 552(b) (1)-(9). No definition of the term "records" is found in either the Act or the legislative history.² The case law, focusing almost exclusively on the exemptions, sheds little light on this term.³ We are thus left with little

¹ [Continued]

The section was amended in 1974 to make clear that "[a] 'description' of a requested document would be sufficient if it enabled a professional employee of the agency who was familiar with the subject area of the request to locate the record with a reasonable amount of effort." H.R. REP. NO. 876, 93d Cong., 2d Sess. 5-6 (1974).

² The 1967 Attorney General's Memorandum does contain one sentence relevant to the definition of agency records. It says: "Subsection (c) [552(a) (3)] refers, of course, only to records in being and in the possession or control of an agency." R. Clark, Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act (1967) reprinted in Freedom of Information Act Source Book, S. REP. NO. 82, 93d Cong., 2d Sess. 222 (1974) (emphasis added). Although the Attorney General's Memorandum is a doubtful guide to congressional intent, see K. DAVIS, ADMINISTRATIVE LAW TREATISE 117 (1970 Supp.), the fact that it refers to two criteria for defining agency "records"—possession or control—suggests a more inclusive approach than that adopted by the majority. I would also argue that the Attorney General's Memorandum is consistent with the result I would reach here, since in my view the Government involvement with the UGDP data amounts to "control."

³ But see *Goland & Skidmore v. CIA*, No. 76-1800 (D.C. Cir., May 23, 1978) (congressional hearing transcript in possession of agency not an agency record); *SDC Development Corp. v. Mathews*, 542 F.2d 1116 (9th Cir. 1976) (materials in medical reference library not agency records); *Cook v. Willingham*, 400 F.2d 885 (10th Cir. 1968) (per curiam) (presentence report in the hands of prison authority not an agency record); *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D. N.Y. 1977) (UGDP raw data not agency records); *Nichols v. United States*, 325 F. Supp. 130 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972) (physical evidence relating to assassination of President Ken-

direct guidance in attempting to elucidate a key provision of the Act.

The majority does not discuss the difficulties involved in defining agency "records." It simply asserts, with little supporting rationale, that the crucial question is whether the documents have been "created" or "obtained" by a federal agency.⁴ In adopting this approach, the majority joins with the federal defendants and the district court in looking to such factors as property rights and possession in defining agency "records."⁵ I have no

nedy not "records"). I exclude cases that turn on the definition of a federal "agency." *E.g.*, *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971).

⁴ Maj. op. at 16. Apparently, the majority would also recognize agency "records" where the Government is involved in the "core planning or execution" of a program, maj. op. at 16 n. 19, 21; and where a federal agency has a duty to obtain records. Maj. op. at 16. But see concurring op. at 1.

⁵ The district court found that

(1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institute of Health (NIH), the Food and Drug Administration (FDA), or the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) . . . ; (2) the raw data in question is [sic] the property of the individual investigators and UGDP coordinating center and remains in the possession, custody and control of the UGDP study coordinating center. . . ; (3) neither the individual investigators nor the UGDP study coordinator is an 'agency' within the purview of the Freedom of Information Act, 5 U.S.C. § 552; and (4) consequently, the raw data in issue are not 'agency records' subject to the disclosure provisions of the Freedom of Information Act, 5 U.S.C. § 552 (B).

Joint Appendix (J.A.) at 146-47 (footnote omitted).

[Continued]

objection to title or custody as relevant criteria. I do object, however, to a test based on only some of many possibly relevant factors, with little justification offered for the primacy of these factors. The place to start in determining the scope of agency "records" is not with assertion, but with an examination of the policies of the FOIA.

There can be no doubt about the basic goals of the Freedom of Information Act. As the Senate Report put it, the fundamental premise of the Act is that "the public as a whole has a right to know what its Government is doing." S. REP. NO. 813, 89th Cong., 1st Sess. 5 (1965). FOIA was designed, in the words of the Report, "to establish a general policy of full agency disclosure unless information is exempted under clearly delineated statutory language. . . ." *Id.* at 3. In the House, Congressman after Congressman rose to speak in support of the policy underlying the bill. This was, as they variously put it, the right to the public "to information relating to the actions and policies of Federal agencies," 112 CONG. REC. 13655 (1966) (remarks of Rep. Hall); "to know the facts about the operation of their government," *id.* at 13657 (remarks of Rep. Reid); "to be fully informed about the policies and activities of the Federal Government," *id.* at 13648 (remarks of Rep. Faschell). These statements suggest the need for a broad definition of agency "records": broad enough to let the public know everything "its Government is doing;" to illuminate all "policies and activities of the Federal Government."

* [Continued]

The federal defendants' position is that "the term 'agency records' in the Freedom of Information Act applies to 'records' in the possession of a federal agency or owned by an agency, or produced under the day-to-day supervision of an agency." Gov. Br. at 17.

The principle that "the disclosure requirement be construed broadly. . . ," *Soucie v. David*, 448 F.2d 1067, 1080 (D.C. Cir. 1971), is also rooted in the structure of FOIA. Before FOIA was enacted, the public information section of the Administrative Procedure Act allowed agencies to withhold information "in the public interest," or "for good cause shown," or if the person seeking the information was not "properly and directly concerned." 5 U.S.C. § 1002 (1964). These broad exemptions created what was in effect a "withholding statute," not a "disclosure statute."⁶ To remedy this situation, Congress enacted a statute containing a general disclosure section and nine narrowly drawn exemptions. The disclosure section provided that "any person" could have access to any agency "record," without having to state a reason for wanting the information. And the exemptions were drafted to provide "definitive guidelines"⁷ as to what information could be withheld. To avoid new loopholes, Congress expressly limited the grounds for nondisclosure to those specified in the exemptions.⁸ The objective was to "make it clear beyond doubt

⁶ S. REP. NO. 813, *supra* at 5.

⁷ *Id.* at 3.

⁸ This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section.

5 U.S.C. § 552(c) (1970).

I agree that in enacting FOIA Congress struck a deliberate balance between a policy of full disclosure and various countervailing policies. Maj. op. at 17. But the legislative history makes it abundantly clear that all of the competing policies Congress saw fit to recognize were to be accommodated through nine specific exemptions. It comes as a surprise, therefore, to learn that a policy not mentioned by Congress—that of preserving grantee "autonomy," maj. op. at 19 is to be realized through a restrictive definition of agency "records."

that all *materials of the Government* are to be made available to the public by publication or otherwise unless explicitly allowed to be kept secret by one of the exemptions in [§ 552(b)]." S.REP.NO. 813, *supra* at 10 (emphasis added in part).

Both the purpose and the structure of FOIA point to a broadly inclusive definition of agency "records"—a definition encompassing "all materials of the Government." I seriously doubt that common law notions of property or custody can define the totality of such records. In my view, the appropriate approach under the statute is to examine *all* the relevant circumstances surrounding the creation, preservation, and use of particular records. If this analysis reveals a significant degree of federal involvement with the records,⁹ then they should be considered agency "records" subject to FOIA.

II.

Plaintiffs emphasize three forms of federal involvement with the UGDP research data: federal funding of the data, federal access to the data, and federal reliance on the data in administrative decisionmaking. We need not decide whether one of these factors, or even two of these factors in combination, would be sufficient to make the

⁹ Another court that has grappled with whether the UGDP raw data are agency "records" concluded "that the goals and purposes of the Act would be served best by imposing a standard which calls for proof that the records were either Government-owned or subject to substantial Government control or use. In other words, it must appear that there was significant Government involvement with the records themselves in order to deem them agency records." *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523, 529 (S.D. N.Y. 1977). Although I disagree with Judge Tenney's application of this standard, particularly his conclusion that the Government has not directly relied on the UGDP raw data, *id.* at 531, I have no quarrel with his statement of the standard itself.

UGDP data agency "records." Where all three factors are present, however, I think these materials are clearly agency "records."

A. Government Funding

One hundred percent of the UGDP funding was provided by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), one of the institutes of the National Institutes of Health. Federal funding is significant for FOIA purposes for two reasons. First, funding of scientific research is a federal activity, and FOIA was enacted to allow the public to obtain information about all federal activities—including the expenditure of money. As one Congressman put it, FOIA was intended in part to enhance the rights and responsibilities of the voting public by making it possible for them to know "what their Government is doing with their money." 112 CONG.REC. 13659 (1966) (remarks of Rep. Gurney); *accord* 110 CONG.REC. 17088 (1964) (remarks of Sen. Dirksen).

Federal funding of the UGDP is also important because funding brings with it significant Government control over the use, maintenance, and disposition of the UGDP raw data. This can be seen by examining HEW regulations governing the relationship between the Government and the grant recipient. Under these regulations, the grantee is obliged to retain "financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant" for a period of three years after receiving the grant. 42 C.F.R. § 74.20. If the granting agency determines that any of the records generated by the grantee have "long term retention value," the agency may order the records transferred to the Government for permanent custody. *Id.* § 74.20(b). At all times, the Government has the right of access to "any books, documents, papers, and records of the grantee"

for the purpose of making "audit, examination, excerpts and transcripts." *Id.* § 74.23(a). The regulations further require that the grantee retain all "[l]aboratory notes, related technical data and information" that pertain to a patentable invention, and make them available to HEW upon request. *Id.* § 52.22. And if the grantee copyrights a publication resulting from the grant, the regulations give the Government a royalty free, nonexclusive license "to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so." *Id.* § 52.23. While these provisions probably fall short of establishing full federal ownership of the UGDP data, *see* Gov. Br. at 26-31, they do establish, I think, that the Government has a substantial degree of control over the use and disposition of the UGDP records.

B. Government Access

Under the HEW grant regulations, the Government has an apparently unlimited right of access to the UGDP raw data. 45 C.F.R. § 74.23(a) provides:

HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit, examination, excerpts and transcripts.¹⁰

¹⁰ The Government may have access to the UGDP raw data under FDA regulations as well. 21 C.F.R. § 312.1(a) (12) (6) (e) gives the FDA the right of access to investigator's records relating to investigational new drugs (INDs). The UGDP holds two INDs from the FDA. J.A. at 92. The federal defendants note that the regulation requires investigators to *retain* such records for only two years after administration of an IND has been discontinued, and assert that the UGDP discontinued use of its INDs more than two years ago. Gov. Br. at 34-35. However, there is no indication that

HEW is permitted to "examine" and "excerpt" not only the financial records of the UGDP, but also raw research records. This is demonstrated by the fact that when the FDA conducted a scientific audit of the UGDP, portions of the raw data were examined by government investigators, copied, and then retained by the agency. Gov. Supp. Memo. of Dec. 5, 1977.

The Government's right of access to the UGDP raw data is important for FOIA purposes since it establishes the basis for Government compliance with FOIA requests. Obviously, the Government must be able to obtain copies of requested agency "records" quickly and without legal impediment.¹¹ For example, if the Government had to purchase certain data, or subpoena certain records to comply with a FOIA request, these materials might not be considered agency "records." We need not decide this question, for no such barrier is involved here. The Government can exercise its right of access to the UGDP data at any time and for any reason. To be sure, greater inconvenience may be involved in obtaining copies of documents not in the immediate custody of the agency. But, as the Government concedes, agency "records" need not be located within the physical confines of the agency.

the UGDP has in fact discarded the records, or that the FDA *right of access* is extinguished two years after administration of an IND stops.

¹¹ The Act requires agencies to determine whether to comply with a FOIA request "within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request. . . ." 5 U.S.C. § 552(a) (6) (A) (1974). An additional 10 days is permitted in "unusual circumstances," including "(i) the need to search for and collect the requested records from field facilities or *other establishments* that are separate from the office processing the request; . . ." *Id.* § 552(a) (6) (B) (i) (emphasis added). The last provision appears to specifically contemplate that agency "records" can be found outside the custody of the agency.

Gov. Br. at 20 n.32. Records may be bailed to a privately-owned warehouse, loaned to a private entity, or may have been sold or donated to the Government but not delivered. In terms of ease of compliance with FOIA, these types of situations are indistinguishable from the present case.¹²

C. Government Reliance

Probably the strongest link between the UGDP data and the Federal Government is found in the extensive history of federal reliance on the UGDP study and data in regulatory action dealing with the treatment of diabetes. This reliance must be viewed against the background of intense controversy surrounding the UGDP ever since the study's first conclusions were published in 1970.¹³

¹² The majority's assertion that *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 161-62 (1975) and *Renegotiation Board v. Grumman Aircraft Engineering Corp.*, 421 U.S. 168, 192 (1975) require more than a mere right of access to documents is without foundation. These cases stand only for the proposition that FOIA does not oblige an agency to write opinions. They say nothing about the duty to retrieve records that are reasonably described, admittedly exist, and are within an agency's power to obtain.

¹³ Klimt, Knatterud, Meinert & Prout, *The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes*, 19 DIABETES (Supp. 2) 747 (1970). Subsequent reports were published in Knatterud, Meinert, Klimt, Osborne & Martin, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: IV. A Preliminary Report on Phenformin Results*, 217 JAMA 777 (1971); Goldner, Knatterud & Prout, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: III. Clinical Implications of UGDP Results*, 218 JAMA 1400 (1971); Knatterud, Klimt, Osborne, Meinert, Martin & Hawkins, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: V. Evaluation of Phenformin Therapy*, 24 DIABETES (Supp. 1) 65 (1975).

Release of the UGDP's initial findings, suggesting a possible correlation between oral hypoglycemic drugs and cardiovascular mortality, had a profound impact.¹⁴ Professional conferences were convened, articles were published, and scientific studies were undertaken with the hope of evaluating the UGDP conclusions and determining their validity. The medical and scientific communities eventually divided along pro- and anti-UGDP lines. Supporters of the UGDP cited the study's cost, duration, broad patient base, and sophisticated design as confirming the validity of the findings.¹⁵ Critics of the UGDP, on the other hand, pointed to alleged inadequacies in study design, methodology, and execution.¹⁶ The controversy was compounded when a UGDP investigator, Dr. Angela Bowen, resigned from the study, challenging the integrity of the program director and suggesting a possible manipulation of the data base to reach results unfavorable to one of the drugs under study.¹⁷

¹⁴ Some of the controversy surrounding the UGDP study is reviewed in the majority opinion at 3-7.

¹⁵ See, e.g., Cornfield, *The University Group Diabetes Program: A Further Statistical Analysis of the Mortality Findings*, 217 JAMA 1676 (1971); Prout, Knatterud, Meinert & Klimt, *The UGDP Controversy: Clinical Trials Versus Clinical Impressions*, 21 DIABETES 1035 (1972).

¹⁶ See, e.g., Feinstein, *Clinical Biostatistics: An Analytical Appraisal of the University Group Diabetes Program (UGDP) Study*, 12 CLIN. PHARMACOLOGY, THERAPEUTICS 167 (1971). Schor, *The University Group Diabetes Program: A Statistician Looks at the Mortality Results*, 217 JAMA 1671 (1971).

¹⁷ Dr. Bowen testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs:

An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has

Despite all the uncertainty about the validity of the UGDP study, and the inability of sceptical scientists and physicians to examine the raw data, the Federal Government has twice relied on the UGDP findings in regulatory action affecting a large segment of the public. In

also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators.

J.A. at 130-31.

1975, the Commissioner of the Food and Drug Administration (FDA) proposed new labeling requirements for oral hypoglycemic drugs used in the treatment of diabetes. 40 FED. REG. 28587 (1975). The *Federal Register* notice of the proposed warning stated in part:

The judgment of the Commissioner that changes must be made in the labeling of the oral hypoglycemic drugs to reflect the findings of the UGDP study is well known. . . .

The warning proposed in this labeling is based primarily on a thorough review and evaluation of the UGDP study. . . .

The Commissioner reaffirms his view that the UGDP study is an adequate and well-controlled clinical trial, which is the most extensive and detailed examination of the long-term administration of hypoglycemic agents yet undertaken.

. . . The Commissioner believes that the UGDP study is a validly conducted trial and accepts the opinion of the Biometric Society committee and other experts that the increased cardiovascular mortality found in this trial cannot reasonably be attributed to scientific shortcomings in the study.

Id. at 28591.¹⁸ A clearer affirmation and reliance on the UGDP study is hard to imagine.

¹⁸ The Commissioner of FDA recognized that "[f]rom the time the results of the UGDP study were first reported, the study was subjected to intense criticism by both clinicians and statisticians." 40 FED. REG. 28588. He conceded that "a wide-spread belief had developed among many physicians that the UGDP study was somehow flawed in terms of its design and execution, and therefore could not serve as a proper basis for a warning to the medical profession." *Id.*

The agency therefore decided to postpone implementation of the warning until [review of the UGDP study by

Later, in 1977, Secretary Califano of HEW declared phenformin, an oral hypoglycemic drug, an "imminent hazard to public health" under § 505(e) of the Food and Drug Act, 21 U.S.C. § 355(e), and suspended approval of all new drug applications for this drug. The Secretary indicated that he was relying to a considerable extent on the statistical evidence gathered by the UGDP. The order stated that "[t]he FDA, which is experienced in interpreting and analyzing incidence figures for adverse reactions, has examined [the UGDP] statistics and concluded that the incidence figures are scientifically valid."

a committee of the Biometrics Society] was published. Since the UGDP study was the basis for the proposed warning, the Commissioner believed that this independent review of the statistical validity of the study should be available to all interested persons before taking definitive action. The review by the committee of the Biometrics Society required extensive reanalysis of the data in the UGDP study and was not published until February 10, 1975.

Id. at 28589.

The Biometrics Society audit reconfirmed the Commissioner's belief in the need for regulatory action based on the UGDP.

Although the [UGDP] has shortcomings, which might be expected in any clinical trial of this complexity, the shortcomings do not invalidate the central finding that there appears to be an increased risk of cardiovascular mortality associated with the administration of tolbutamide and of phenformin to maturity-onset diabetic patients, compared to treatment with diet alone or diet plus insulin. This conclusion has in the past been reached independently by the UGDP investigators, the FDA, and the Biometrics Society committee, and is again affirmed by the Commissioner. Other clinical trials of these oral hypoglycemic drugs are not comparable to the UGDP study and provide insufficient evidence to negate the findings of the UGDP study.

Id. at 28591.

Order of the Secretary Suspending Approval at 11 (July 25, 1977).¹⁹

Significantly, the proposed labeling change and suspension of phenformin were not undertaken solely on the basis of the published studies of the UGDP. In addition, the Federal Government has twice exercised its right of access to the UGDP raw data to verify the validity of the UGDP findings. When the initial controversy over the UGDP erupted, NIAMDD retained an independent group of biostatisticians, the Biometric Society, to review the UGDP. The Society was given access to the UGDP raw data for this purpose. After conducting a partial audit, it published a report indicating support for the UGDP findings.²⁰ Several years later, prior to the suspension of new drug applications for phenformin, the FDA conducted its own audit of the UGDP. Details of this audit are sketchy, but the federal defendants admit that the FDA examined and copied at least a sample of the UGDP data in the course of its examination of the study. Gov. Supp. Mem. of Dec. 5, 1977 at 2.

These Government-sponsored or conducted audits are of considerable importance. By examining the UGDP raw data at first hand, the Government has apparently satisfied itself that the UGDP results are sound. In other words, the Government has relied *directly* on the UGDP raw data in the course of formulating official Government policy. As such, these data are precisely the sort of docu-

¹⁹ The quoted passage refers to statistics from "all available sources," Order at 11, but it is clear from the context that the UGDP is included. The UGDP is also referred to at pp. 8, 38, 40-41, 46, 63 and 66.

²⁰ Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents, *Report of the Committee for the Assessment of Hypoglycemic Agents*, 231 JAMA 583 (1975).

ments Congress intended to be disclosed under FOIA. *SDC Development Corp. v. Mathews*, *supra* n.3, at 1119-20.²¹

III.

The majority cryptically asserts that a finding that the UGDP raw data are agency "records" would interfere with the "autonomy" of federal grant recipients. The exact meaning of this is unclear. I do not maintain, nor do plaintiffs argue,²² that the UGDP is a federal "agency." Consequently, no suggestion has been made that all of the various duties and responsibilities of a federal agency should be imposed on the UGDP. The only question before us is whether the UGDP raw data are agency "records" of HEW. An affirmative answer to this question would require *HEW*—not the UGDP—to obtain copies of these records in response to plaintiffs' FOIA request. No direct interference with the manner or method in which a grantee conducts its research would result.

Perhaps the majority's reference to "autonomy" means to suggest that scientific activity would be chilled by the knowledge that data produced under a federal grant

²¹ In emphasizing the Government's reliance on the UGDP study and data, I do not imply that the court should give weight to plaintiffs' "need" for the UGDP raw data, or to plaintiffs' position as litigants in the phenformin suspension proceedings. *Maj. Op.* at 10-11. *See NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975). My point is simply that, because of the Government's reliance, the UGDP data have been absorbed into the federal decision-making process. This factor, together with the factors previously mentioned—federal funding and federal right of access—satisfies me that the UGDP raw data are agency "records." They should therefore be potentially available for disclosure to all members of the public.

²² Plaintiffs do not challenge the district court's ruling, *see n.4 supra*, that the UGDP is not a federal "agency." *Pet. Br.* at 28 n.7.

could, in limited circumstances, become agency "records." This has been advanced elsewhere as a policy reason for not finding the UGDP data to be agency "records."²³ On closer examination, however, I think even this concern carries little force.

The notion that a chilling effect could result from subjecting the records of federal grantees to disclosure could refer to one of three things. First, it could refer to the possibly inhibiting effect of a visit to the laboratory by a federal official executing a FOIA request. As a basis for restricting FOIA, I find this implausible in the extreme. The inconveniences occasioned by an infrequent FOIA request would be no greater than those currently created by conditions attached to the grant, including the possibility of Government inspection.²⁴ Yet these burdens appear to have had an imperceptible effect on the enthusiasm for federal research grants.

Secondly, the chilling effect notion could refer to the danger that unscrupulous scientists would use FOIA to appropriate valuable research data for their own credit—or profit. This is a legitimate concern, and if all grantee research records were subject to FOIA it could conceivably deter some scientists from seeking federal grants. But the danger of misappropriation is minimal where, as here, the Government has relied on scientific records in the course of its decisionmaking. Government reliance will likely be limited to cases where the results of the study have been previously published or announced. Thus, whatever weight this concern is entitled to in other con-

²³ *Ciba-Geigy Corp. v. Mathews*, *supra* n. 3 at 530.

²⁴ As noted above, HEW grant regulations already give the Government an unlimited right to inspect grantee records. *See pp. 7-8 supra*. This right was in fact exercised in this case when the FDA audited the UGDP data.

texts, it is of little significance where the element of reliance is present.

Finally, federal grant applicants might be inhibited by having methodological or investigatory flaws in their work uncovered through a FOIA request. If *this* is the danger the majority seeks to avoid under the guise of protecting grantee "autonomy," then it is a sad day for both the scientific community and the Freedom of Information Act. The essence of the scientific community, I had thought, is the commitment to the advancement of scientific truth by subjecting findings and conclusions to the "exacting scrutiny of fellow experts."²⁵ Moreover, where scientific data bear the earmarks of agency "records" subject to FOIA, it would be the height of irony to deny disclosure on the ground that it could expose errors or frauds and thereby discourage those who do the work of the Government. FOIA was enacted in part to end the practice of withholding information "only to cover up embarrassing mistakes or irregularities. . . ." S.REP. No. 813, *supra*, at 3. To restrict the definition of agency "records" to accomplish the same end could only be regarded as a giant leap backwards.

I respectfully dissent.

²⁵ R. MERTON, *THE SOCIOLOGY OF SCIENCE* 275 (1973); see also B. BARBER, *SCIENCE AND THE SOCIAL ORDER* 89 (1952).

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

February 5, 1976

PETER H. PORSHAM, et al., *Plaintiffs*,

v.

DAVID MATHEWS, et al., *Defendants*.

Order

Upon consideration of plaintiffs' motions for summary judgment and expedited relief, defendant Klimt's motion to dismiss and to quash service of process, federal defendants' motion to dismiss or in the alternative, for summary judgment, the oppositions thereto, the memoranda of the parties in support thereof and in opposition thereto, and the entire record herein, the Court finds that (1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the National Institutes of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) (*See* Affidavits of Theodore M. Cooper, M.D. and G. Donald Whedon, M.D., Federal Defendants' Motion to Dismiss or, in the alternative, for Summary Judgment); (2) the raw data in question is the property of the individual investigators and UGDP study coordinating center and remains in the possession, custody and control of the UGDP study coordinating center (*See* Affidavit of G. Donald Whedon, M.D., *supra*); (3) neither the individual investigators nor the UGDP study coordinating

center is an "agency" within the purview of the Freedom of Information Act, 5 U.S.C. § 552;¹ and (4) consequently, the raw data in issue are not "agency records" subject to the disclosure provisions of the Freedom of Information Act, 5 U.S.C. § 552(B).

It is, accordingly, by the Court this 5th day of February, 1976,

ORDERED that plaintiffs' motion for summary judgment should be, and the same is hereby, denied. And it is further

ORDERED that defendants' motions to dismiss should be, and the same are hereby, granted.²

/s/ HOWARD CORCORAN
Judge

¹ For purposes of the FOIA, an "agency" includes "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." 5 U.S.C. § 552(e).

² The remaining motions for expedited relief and to quash service of process are denied as moot.

APPENDIX D

5 U.S.C. § 552

Title 5

Government Organization and Employees

CHAPTER 5—ADMINISTRATIVE PROCEDURE

Part I—The Agencies Generally

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

§ 552. Public information: agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general

policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967,

and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(4)(A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges for document search and duplication. Documents shall be furnished without charge or at a reduced charge where the agency determines that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

(C) Notwithstanding any other provision of law, the defendant shall serve an answer to otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the

withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall—

(i) determine within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request—

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for

records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(b) This section does not apply to matters that are—

(1) (A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the

case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include—

(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by such agency regarding this section;

(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and

(7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(e) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383; Pub.L. 90-23, § 1, June 5, 1967, 81 Stat. 54; Pub.L. 93-502, §§ 1-3, Nov. 21, 1974, 88 Stat. 1561-1564; Pub.L. 94-409, § 5(b), Sept. 13, 1976, 90 Stat. 1247.

APPENDIX E**HEW REGULATIONS GOVERNING ADMINISTRATION OF
GRANT RESEARCH****Title 45—Public Welfare****Subtitle A—Department of Health, Education, and Welfare****Part 8—Inventions and Patents (General)****§ 6.1 Publication or patenting of inventions.**

It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made where the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Commissioner of Patents. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

[23 FR 2990, Mar. 27, 1963. Redesignated at 31 FR 12842, Oct 1, 1966]

Title 45—Public Welfare**Subtitle A—Department of Health, Education, and Welfare****Part 8—Inventions Resulting From Research Grants, Fellowship Awards, and Contracts For Research****§ 8.0 Policy.**

(a) The Department of Health, Education, and Welfare each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsibility to see that the public use of the

fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

§ 8.1 Conditions to be included in research grants.

Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide either

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the Assistant Secretary (Health and Scientific Affairs) finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be

prescribed, to file foreign patent applications upon the invention.

[20 FR 6749, Sept. 14, 1965, as amended at 31 FR 12842, Oct. 1, 1966]

Title 45—Public Welfare

Subtitle A—Department of Health, Education, and Welfare

Part 74—Administration of Grants

Subpart D—Retention and Custodial Requirements for Records

§ 74.20 Length of retention period.

HEW will not impose record retention requirements over and above those established by the grantee except that financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant shall be retained for a period of three years. This requirement applies to the pertinent records and documents of grantees, subgrantees, and recipients under grants or subgrants of negotiated contracts (or subcontracts) exceeding \$10,000. The requirement is qualified as follows:

(a) If audit by or on behalf of the Federal Government has begun but is not completed at the end of the three-year period, or if audit findings have not been resolved at the end of the three-year period, the records shall be retained until resolution of the audit findings. In no case, however, will HEW require retention of records relating to any grant with respect to which actions by the United States to recover for diversion of money paid under the grant are barred by the statute of limitations in 28 U.S.C. 2451(b).

(b) In order to avoid duplicate recordkeeping, granting agencies may make special arrangements with grantees to retain any records which are continuously needed for joint use. The granting agency will request transfer of records to its custody from grantees when it determines that the records possess long-term retention value. When the rec-

ords are transferred to or maintained by HEW, the three year retention requirement is not applicable to the grantee.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.23 Access to records.

(a) HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit; examination, excerpts and transcripts.

(b) In the case of a subgrant (or negotiated contract or subcontract exceeding \$10,000) under a HEW grant, the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee (or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives determine are pertinent to the specific HEW grant, for the purpose of making audit, examination, and transcripts.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.24 Restrictions on public access.

Unless otherwise required by law, HEW will not place restrictions on grantees which will limit public access to the grantee's records or to the records of their subgrantees

or contractors, except when the records must remain confidential for any of the following reasons:

(a) To prevent a clearly unwarranted invasion of personal privacy;

(b) To comply with an executive order or statute which specifically requires the records to be kept secret; or

(c) To protect commercial or financial information obtained from a person or firm on a privileged or confidential basis.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44553, Oct. 8, 1976]

APPENDIX F

Pertinent FDA Regulations Governing Disclosure of Data

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding up to that time. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be placed on public display and shall not be part of the administrative record of that proceeding.

(2) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(3) All other documentary data and information on which he relies.

(4) A narrative statement of his position on the factual issues stated in the notice of hearing and the type of evidence he intends to introduce in the hearing in support of his position.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published in the FEDERAL REGISTER pursuant to § 12.35, or, where no participant will be prejudiced, within such shorter or longer period of time as the presiding officer orders, each

participant shall submit to the Hearing Clerk all data and information specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a) (1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen at that time.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall also constitute a waiver of the right to a hearing.

(e) Any documentary data and information submitted by one participant may be referenced by another. Participants are encouraged to exchange and consolidate lists of documentary evidence prior to reproducing it for submission to the Hearing Clerk in order to reduce duplicative submissions. If a particular document is bulky or is in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, a participant may request the presiding officer for permission to submit a reduced number of copies to the Hearing Clerk.

(f) The presiding officer shall rule on questions relating to this section.

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

Part 20—Public Information

Subpart F—Availability of Specific Categories of Records

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

Part 312—New Drugs For Investigational Use

Subpart A—Exemptions From Section 505(a)

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

. . .

(4) The sponsor maintains adequate records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of a scientifically trained and properly authorized employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in paragraph (a)(2) of this section available for inspection, and upon written requests submits such records or copies of them to the Food and Drug Administration. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

. . .

(13) The sponsor shall obtain from each investigator involved in clinical trials a signed statement in the following form:

Form FD-1573

Department of Health, Education, and Welfare, Food and
Drug Administration

Statement of Investigator

• • •

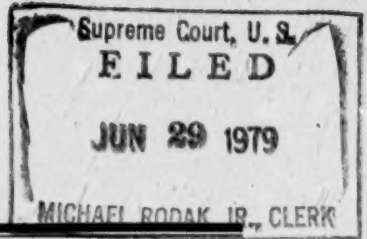
4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipts and use of this investigational drug:

• • •

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new drug application is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.

78-1118

APPENDIX



IN THE
Supreme Court of the United States
OCTOBER TERM, 1978

—
No. 1118
—

PETER H. FORSHAM, ET AL.,
Plaintiff-Petitioners,

v.

JOSEPH A. CALIFANO, JR., ET AL.,
Defendant-Respondents.

—
On Writ of Certiorari to the United States Court of Appeals
For the District of Columbia Circuit
—

Petition for Writ of Certiorari filed January 15, 1979
Certiorari Granted May 14, 1979

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RELEVANT DOCKET ENTRIES**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

DATE NR. PROCEEDINGS

1975

Sept 30—COMPLAINT, appearance; Affidavits (3); P & A's;
Exhibits A thru V

. . .

Oct 21—MOTION by pltfs. for expedited relief; c/m

Oct 31—MOTION by deft. #5 to dismiss and to quash service of process.

. . .

Nov 21—MOTION by federal defts. to dismiss or in the alternative for summary judgment on behalf of the federal defts.; and exhibit 1; exhibit 3.

Nov. 24—MOTION by pltfs. for leave to file opposition to motion to dismiss; exhibits (2); exhibits B, C, D; c/m.

Dec. 5—OPPOSITION by pltfs. to defts. motion for summary judgment; motion for summary judgment; memorandum; exhibit A; attachment A,B; exhibit B; c/m 12-4.

Dec 5—REPLY memorandum by deft. #5 in support of motion to dismiss and to quash service of process; affidavit of Christian R. Klimt; attachment; c/m 12-5.

1976

. . .

Feb 5—ORDER denying motion of pltfs. for summary judgment and granting motion of defts. to dismiss. (N) Corcoran, J.

. . .

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

1977

(C)9-14-77—4-Appellants' motion for further hearing (m-13)

DATE NR. PROCEEDINGS
1977

- (T)9-23-77—4-Appellees' opposition to motion for further hearing (m-23)
- (T)10-26-77- 4-Appellants' additional allegations to motion for further hearing (m-26) (OK RB)
- (T)11-3-77—4-Appellee's (Federal) response to appellants' additional allegations to motion for further hearing (m-3)
- (E)11-16-77—Per Curiam order, sua sponte, that the parties to this appeal are directed to file supplemental memoranda, on or before December 5, 1977, addressing the following questions: (see order for details: Bazelon, CJ, Leventhal and MacKinnon, CJ's)
- (T)12-5-77—4-Appellee's (Christian Klimt) supplemental memorandum in response to order of 11/16 (m-1)
- (T)12-5-77—4-Appellees' (Federal) supplemental memorandum in response to order of 11/16 (m-5)
- (T)12-5-77—4-Appellants' supplemental memorandum in response to order of 11/16 (m-5)

1978

- (R)7-11-78—Opinion for the Court filed by Circuit Judge Leventhal
- (R)7-11-78—Concurring opinion filed by Circuit Judge MacKinnon
- (R)7-11-78—Dissenting opinion filed by Circuit Judge Bazelon
- • •
- (T)7-25-78—10-Appellants' petition for rehearing and suggestion for rehearing en banc (m-25)
- • •
- (R)10-17-78—Statement of Circuit Judge Bazelon as to why he voted for rehearing
- • •

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIVIL ACTION No.:

PETER H. FORSHAM, HENRY DOLGER, HOLBROOK S. SELTZER,
as they are members of the Committee on the Care of
the Diabetic, *Plaintiffs*,

v.

DAVID MATHEWS, Secretary of the Department of Health,
Education, and Welfare
THEODORE COOPER, Assistant Secretary of Health, Department of Health, Education and Welfare
ALEXANDER M. SCHMIDT, Commissioner of the Food and Drug Administration
G. DONALD WHEDON, Director of the National Institute of Arthritis, Metabolism, and Digestive Disease
CHRISTIAN R. KLIMT,

Defendants

**COMPLAINT
JURISDICTION**

1. This is an action pursuant to the provisions of the Freedom of Information Act (FOIA) 5 U.S.C. § 552, as amended, to enjoin the defendants from withholding reasonably identifiable agency records requested by plaintiffs and to compel the production of such records.

2. This is also an action pursuant to the provisions of 28 U.S.C. §§ 2201-2 for a declaratory judgment that defendants' withholding of records as set forth herein is unauthorized by and contrary to law, and for injunctive and other relief.

3. Jurisdiction of this Court is invoked pursuant to the provisions of 28 U.S.C. § 1331, 5 U.S.C. § 552 and 28 U.S.C.

§§ 2201-2. There exists between the parties an actual controversy, justiciable in character, in respect of which plaintiffs require a declaration of their rights by this Court. The matter in controversy exceeds the sum of \$10,000, exclusive of interests and costs.

PARTIES

4. The Committee on the Care of the Diabetic (CCD) is an unincorporated association of 178 physicians in the United States who are involved in the daily management and treatment of diabetes mellitus, a disease affecting millions of Americans. Since its inception in 1970, the primary purpose of CCD has been to assure that both the patients who suffer from diabetes mellitus and the physicians who treat it are provided with full, accurate, and truthful information concerning the safety and efficacy of medications prescribed for its treatment. Plaintiffs, all members of CCD, are as follows:

a. Peter H. Forsham, a resident of Mill Valley, California, is Professor of Medicine and Pediatrics, Director of the Metabolic Research Unit, and Chief of Endocrinology at the University of California Medical Center, School of Medicine, San Francisco, California. He is author of more than two hundred and fifty medical and scientific papers in the field of endocrinology and metabolism, notably diabetes and diseases of the adrenal and pituitary glands. He also is Chairman of The Coordinating Committee of CCD;

b. Henry Dolger, a resident of New York City, New York, is Clinical Professor of Medicine, Attending Physician and Chief of the Diabetes and Pre-Natal Diabetes Clinics at the Mt. Sinai Hospital, New York. He is Consultant in diabetes at Elmhurst General Hospital and Kingsbridge Veterans Hospital. He is also author of "How to Live With Diabetes" and thirty-six other publications and monographs relative to diabetes. He is also a member of The Coordinating Committee of CCD;

c. Holbrook S. Seltzer, a resident of Dallas, Texas is Chief of the Metabolic Section at the Veterans Administration Hospital and a Professor of Internal Medicine at the University of Texas Southwestern Medical School in Dallas. He is the author of a report entitled "A Summary of Criticism of the Findings and Conclusions of the University Group Diabetes Program (UGDP)". He has been involved in the treatment and management of thousands of diabetic patients over the last twenty years and is a member of the Coordinating Committee of CCD.

5. The defendants are as follows:

a. Defendant David Mathews is Secretary of the Department of Health, Education, and Welfare (DHEW) which consists of the Office of the Secretary and the several operating agencies;

b. Defendant Theodore Cooper is Assistant Secretary of Health of DHEW and, as such, is responsible for issuing final administrative decisions based on requests for DHEW records under FOIA.

c. Defendant G. Donald Whedon is Director of the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD), a Division of the National Institutes of Health (NIH), an operating agency within DHEW.

d. Defendant Alexander M. Schmidt is Commissioner of the Food and Drug Administration (FDA), an operating agency within DHEW.

e. Defendant Christian R. Klimt is the Director of the Division of Clinical Investigation at the University of Maryland School of Medicine and Director of the Coordinating Center for the University Group Diabetes Program. In the latter capacity, he is custodian of the records sought below.

STATEMENT OF THE CASE

6. From 1961 to the present, NIAMDD has sponsored and supported a study known as the University Group Diabetes Program (UGDP), whose purpose has been to evaluate the effect of oral hypoglycemic treatment on the management and control of diabetes mellitus. This support has taken the form of a series of initial and supplemental grants to twelve participating clinics in the United States.

7. The UGDP filed its first Notice of Claimed Investigational Exemption for New Drugs (IND) in 1967, five years after enactment of the IND provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(i). A second IND was filed in 1971. (Exhibit U attached)

8. The UGDP has involved more than one thousand subjects whose condition was evaluated at the beginning of the study (baseline) and at three-month intervals thereafter. The results of the tests performed on such subjects were recorded on forms standardized for all twelve clinics; copies of which were forwarded to the UGDP Coordinating Center for storing, processing, and analysis. The UGDP raw data referred to hereafter consist of the forms transmitted to the Coordinating Center and the computer tapes and/or programs on the basis of which analysis was conducted of the data contained in such forms.

9. In December 1970, the UGDP published a report on the first eight years of its research (*Diabetes* Vol. 19; Supp. 2, 1970). The UGDP report suggested a possible relationship between oral hypoglycemic drugs and cardiovascular complications in patients suffering from diabetes mellitus.

10. From 1970 to the present, the FDA has sought to require a relabeling of oral hypoglycemic drugs based on the results of the UGDP.

11. On October 7, 1971, CCD petitioned the FDA to rescind proposed agency action involving relabeling of oral

hypoglycemic drugs and to withhold future action pending independent corroboration of UGDP findings. Alleging that the UGDP contained basic flaws in methodology and conclusions, CCD further requested . . .

that the Food and Drug Administration make available to your petitioners and other qualified researchers the baseline data of the University Group Diabetes Program; such baseline data shall include the total patient record of each patient included in the study. (Exhibit A attached).

12. In refusing to rescind its action on June 5, 1972, the FDA endorsed the reliability of the UGDP study and urged that it be given serious consideration by the medical profession. In response to CCD's request for access to the UGDP raw data, the FDA stated as follows:

Your petition states that the results of the UGDP study are not available and therefore not subject to the usual critical review. *We have been assured that the UGDP personnel will honor any reasonable request for data and information.* (Letter of Charles C. Edwards, Commissioner, to Neil L. Chayet, Counsel for CCD, June 5, 1972, p. 8) (Emphasis supplied).

13. On August 11, 1972, CCD brought an action in the United States District Court for the District of Massachusetts (*Bradley v. Richardson*, No. 72-2517-M) seeking declaratory and injunctive relief to prevent the FDA from ordering a relabeling of oral hypoglycemic drugs. CCD further requested

that the Food and Drug Administration make available to the plaintiff physicians the baseline data of the University Group Diabetes Program and that such baseline data include the total patient record of each patient included in the study.

14. On November 3, 1972, the United States District Court issued a preliminary injunction enjoining the FDA-ordered relabeling pending hearing on the merits. The FDA appealed from the granting of the preliminary injunction to the United States Court of Appeals for the First Circuit.

15. On July 31, 1973, the Court remanded the question of drug relabeling to the FDA for further consideration. *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973). Referring to CCD's several requests for access to the UGDP raw data, the Court stated as follows:

... Where the correctness of factual findings are involved or where the complainants request the full record, we think the agency must produce it in court [citing cases]. *Bradley v. Weinberger*, 483 F. 2nd 410, fn. 4 (1st Cir. 1973).

16. On October 15, 1974, following the continued unavailability of the raw data to CCD and the disclosure of portions of such data to other parties i.e., a committee of the Biometric Society reviewing the UGDP pursuant to contract with NIAMDD, CCD telegraphed defendant Whedon requesting: (a) a copy of the draft Biometric report; and (b) immediate access to the data (Exhibit C attached).

17. On October 21, 1974, defendant Whedon denied CCD's request for a copy of the draft Biometric report and failed to respond to its request for access to the data (Exhibit D attached).

18. In a letter to FDA General Counsel on November 4, 1974, CCD renewed its request for a copy of the draft Biometric report and for access to the raw data on the basis of both the Freedom of Information Act and the prior disclosure and circulation of such records (Exhibit E attached).

19. On November 11, 1974, FDA General Counsel forwarded CCD's request to General Counsel for the Public Health Service (Exhibit F attached).

20. On November 22, 1974, General Counsel for the Public Health Service forwarded CCD's request to defendant Whedon at NIAMDD (Exhibit G attached).

21. On December 3, 1974, through its Freedom of Information Officer, DHEW again denied CCD's request for a copy of the draft Biometric report and failed to respond to the request for access to the raw data (Exhibit H attached).

22. On January 2, 1975, CCD requested administrative review and reconsideration of the DHEW action of December 3, 1974 (Exhibit I attached).

23. On January 27, 1975, CCD received from defendant Whedon a copy of the *final* Biometric report on the UGDP. Defendant Whedon further stated that "no one in DHEW has ever had any of the raw data of the UGDP study" (Exhibit J attached).

24. From May-August 7, 1975, CCD renewed its requests for the UGDP raw data and the draft Biometric report in exchanges of communication with defendant Cooper in his capacities as DHEW Assistant Secretary for Health and as final administrative authority under the Freedom of Information Act (Exhibits K-N attached). In addition, CCD requested further specific information concerning the UGDP and its investigators (Exhibit O attached), which information, with several exceptions, was provided by NIAMDD (Exhibit P attached).

25. On August 7, 1975, defendant Cooper notified CCD that neither the FDA nor NIH had ever reviewed or seen the UGDP raw data and that proposed FDA relabeling of the oral hypoglycemic drugs was based solely on UGDP publications and the final Biometric report. He further in-

licated that the raw data was stored in a bank vault in the State of Maryland under the control of defendant Klimt and concluded as follows:

It appears, therefore, that the raw data is the property of the individual investigators and the coordinating center. Given that this is the case,

WHEREFORE, plaintiffs respectfully pray:

1. That this Court issue an order pursuant to the provisions of 5 U.S.C. § 552, as amended, directing the defendants, David Mathews, Theodore Cooper, Alexander M. Schmidt and G. Donald Whedon, in their respective capacities as Secretary of DHEW, Assistant Secretary for Health, Commissioner of the FDA, and Director of NIAMDD, and defendant Christian R. Klimt, in his capacity as principal investigator of the UGDP study and as custodian of records produced during such study to produce: (1) Raw data of the University Group Diabetes Program, which may be in the possession of any of the defendants or as to which they may have a right of access and which consist of the following: (a) the original data as transmitted to the UGDP Coordinating Center by each of the twelve participating clinics; (b) the computer tapes containing statistical analyses of morbidity and mortality based on such data; (c) the computer programs developed by the UGDP Coordinating Center to carry out the foregoing analyses; and (2) the draft report of the Biometric Committee reviewing the UGDP pursuant to contract with NIAMDD.

2. That this Court issue a declaratory judgment that plaintiffs are entitled to the foregoing records under applicable provisions of law and permanently enjoin the defendants from refusing to produce said records.

3. For such other or further relief as may be appropriate.

Respectfully submitted,

CHAYET AND SONNENREICH, P.C.

By /s/ NEIL L. CHAYET
Neil L. Chayet

/s/ HARVEY W. FREISHTAT
Harvey W. Freishtat

Attorneys for Plaintiffs

6 Fayette Street
Boston, Massachusetts
617/357-0202

VETERANS ADMINISTRATION HOSPITAL

4500 S. Lancaster Road
Dallas, Texas 75216

AFFIDAVIT OF HOLBROOKE S. SELTZER, M.D.

I, Holbrooke S. Seltzer, being duly sworn, hereby depose and say as follows:

I am Chief of the Metabolic Section of the Veterans Administration Hospital and a Professor of Internal Medicine at The University of Texas Southwestern Medical School in Dallas, Texas.

I am a clinician who has spent more than 20 years of his professional life in the close management of more than 1,000 patients with diabetes mellitus.

Since its inception in November, 1970, I have been one of the members of the Coordinating Committee of the Committee on the Care of the Diabetic (CCD), and I have written a report entitled "A Summary of Criticisms of the Findings and Conclusions of the University Group Diabetes Program (UGDP)," which was published in Diabetes, volume 21, pages 976-979, in September, 1972.

Since the first publication of the UGDP findings in 1970, the study has been the subject of great controversy among diabetologists, epidemiologists, cardiologists, pharmacologists, biometricians and mathematicians within the medical and scientific communities. The criticism has focused on the inadequacies of the UGDP in terms of design, methodology, execution, interpretation, and even in matters of integrity. Some of the major criticisms are the following: (1) At least one out of every 14 patients in the study did not even have diabetes. (2) The patients used in some of the 12 treatment centers were much sicker before treatment than those admitted to other clinics; and the centers that enrolled the sickest patients had the highest mortality in all

treatment groups. (3) Actually, the two clinics that enrolled the greatest number of already-sick patients subsequently contributed 40%-50% of all deaths in all four treatment groups. This means that the remaining 50%-60% of deaths distributed throughout the other 10 treatment centers represents an inconsequential finding; in other words, the entire "UGDP Controversy" arose because of excessive mortality in only two of the 12 clinics. (4) A fixed dosage of tolbutamide (Orinase) was used in all tolbutamide-treated patients; since this is never done in clinical practice (the dosage is changed according to the patient's response), this means that some patients were over-dosed and others were under-dosed at various times. (5) In evaluating the results, no attention was paid to other uncontrolled variables that are known to influence cardiovascular mortality (obesity, high blood pressure, high blood cholesterol, smoking history, etc.). The many other criticisms of the UGDP study are summarized in the article cited above.

Fundamentally, all of these criticisms come down to the same roadblock—namely, the unavailability of the raw data for review and examination. If the data were made available for review, they would demonstrate the presence or absence of the 15 indices of pre-existing cardiovascular and non-cardiovascular disease that were obtained on each of the 823 patients before assignment to any of the four original treatment groups.

The unavailability of the data has not been due to oversight, since the CCD has been requesting access to it for four years. I personally discussed the need for such an impartial review with the Biometric Committee on January 9, 1973.

Only via a thorough review of the raw data can the following long-standing questions and criticisms be resolved: (1) What was the frequency of total cardiovascular risk factors (as originally defined in the UGDP progress reports) in each patient in all 12 of the treatment centers? (2) Were

more patients with a greater number of combined cardiovascular risk factors randomly assigned to the tolbutamide-treatment group than to the placebo group or either of the insulin-treated groups? (3) Did the tolbutamide-treated patients who died of cardiovascular causes have greater individual totals of the 8 baseline cardiovascular risk factors (as has been charged) than those who died of cardiovascular disease in the other three treatment groups?

Without such answers I find it difficult to know what to tell my patients about the safety or efficacy of the oral hypoglycemic drugs. That is why I have long been involved in the effort to secure access to the raw data.

It has always seemed to me that the UGDP investigators would themselves have welcomed this opportunity to settle the controversy once and for all, by allowing the raw data to be examined. I know that, as a research scientist who has performed clinical research for 19 years with funds provided by the Veterans Administration and the U. S. Public Health Service (National Institutes of Health), I have always considered it my responsibility to disclose the raw data obtained on subjects and patients to either of these supporting agencies upon request.

However, if access to the raw data continues to be denied by the UGDP investigators to any outside review, than I believe members of the medical community have a responsibility to ensure the accuracy and veracity of the study, particularly when a government agency is proposing to use results of that study to require changes in the management and control of patients with diabetes mellitus.

I continue to hope that, through disclosure of data in the very near future, both physicians and patients will soon have answers to the questions they have long been asking.

/s/ HOLBROOKE S. SELTZER, M.D.
Holbrooke S. Seltzer, M.D.

September 27, 1975

Then personally appeared before me the above-named Holbrooke S. Seltzer, M.D., and made oath that the contents of the foregoing affidavit are true to the best of his knowledge and belief, and said Holbrooke S. Seltzer, M.D. signed the foregoing affidavit in my presence.

/s/ ARTHUR F. HERRON
Arthur F. Herron
Notary Public

September 27, 1975
Dallas, County, Texas

Affidavit

As the Chairman of the Committee on the Care of the Diabetic, I wish to state as follows: The undersigned, who has been with the Committee since its inception, does not believe in the validity of a number of conclusions drawn by the UGDP investigators. Since he feels that there is a real need for final clarification of the controversial points in the UGDP investigation, he wishes to gain access for the Committee on the original or so-called raw data that were obtained in this study. This is being done in the interest of the diabetic public being treated with oral hypoglycemic agents at this time and in the future.

Since these original data from the study have not been made available to us to date, we have no choice but to invoke the Freedom of Information Act in order to obtain these data, preferably through the National Institutes of Health, who should have access to them at our request.

/s/ PETER H. FORSHAM
Peter H. Forsham, M.D.
Professor of Medicine and Pediatrics
University of California, San Francisco
and Chairman of the CCD

PHF:kdd

STATE OF CALIFORNIA
COUNTY OF SAN FRANCISCO

On September 26, 1975 before me, the undersigned, a Notary Public in and for said County and State, personally appeared PETER H. FORSHAM, M.D. known to me to be the person whose name is subscribed to the within instrument and acknowledged that he executed the same.

WITNESS my hand and official seal.

/s/ ALICE M. HERRERA
Alice M. Herrera,
Notary Public

List of Exhibits

- A—October 7, 1971 Petition of CCD
- B—First Circuit Opinion in Bradley v. Weinberger
- C—October 15, 1974 telegram to G. Donald Whedon
- D—October 18, 1974 telegram from G. Donald Whedon
- E—November 4, 1974 letter to Peter Barton Hutt
- F—November 11, 1974 letter from Peter Barton Hutt
- G—November 22, 1974 letter from Assistant General Counsel for Public Health
- H—December 3, 1974 letter from DHEW Freedom of Information Officer
- I—January 2, 1975 letter to Charles C. Edwards, Assistant Secretary DHEW and reply
- J—January 27, 1975 letter from G. Donald Whedon
- K—May 6, 1975 letter to Theodore Cooper
- L—May 23, 1975 letter from Theodore Cooper
- M—June 3, 1975 letter to Theodore Cooper
- N—July 8, 1975 letter to Theodore Cooper
- O—July 11, 1975 letter to Linden Neff
- P—July 30, 1975 reply from Russell Roberts F.O.I.A. Officer
- Q—August 7, 1975 letter from Theodore Cooper
- R—August 7, 1975 letter to Theodore Cooper
- S—CCD "Statement on the Treatment of Diabetes"
- T—UGDP Revised Protocol, 1961
- U—September 19, 1975 letter from Sam D. Fine
- V—September 26, 1975 letter to Richard Merrill

EXHIBIT A

CHAYET and FLASH
Counsellors at Law

15 Court Square
Boston, Massachusetts 02108
Area Code 617 523-6511

October 7, 1971

Commissioner of Food and Drugs
Department of Health, Education and Welfare
Washington, D.C. 20204

Dear Sir:

I am herewith transmitting a petition relative to the Food and Drug Administration's actions based on the agency's acceptance of and extrapolations from the conclusions of the University Group Diabetes Program.

I would appreciate a prompt reply to this petition and would hope that in any case, one could be received within 30 days.

I anticipate that the petition will be printed in the Federal Register in the usual course. Kindly address your reply to me at the above address.

Very truly yours,

/s/ NEIL L. CHAYET
Neil L. Chayet

NLC:mm

Commissioner of Food and Drugs
Department of Health, Education, and Welfare
Washington, D.C. 20204

Dear Sir:

This petition is submitted with respect to (1) the issuance of recommendations contained in the October, 1970 FDA Current Drug Information Bulletin entitled, "Diabetes Prescribing Information" and (2) the recommended changing of the INDICATIONS AND WARNINGS section of the labelling of all sulfonylureas as stated in the June 23, 1971, FDA Drug Bulletin.

Attached hereto, in quintuplicate and constituting a part of this petition are the following:

- A. The FDA Current Drug Information, October, 1970 (marked Appendix A).
- B. Relevant excerpts from FDA Drug Bulletin dated June 23, 1971 (marked Appendix B).
- C. Written communications of Robert F. Bradley, M.D. and the Committee on the Care of the Diabetic to the FDA. (marked Appendix C).
- D. A statement of the grounds upon which your petitioner relies for the action requested herein (marked Appendix D).

The recommendations which are the subject of this petition have been made by the Food and Drug Administration (FDA) as a result of the report of the University Group Diabetes Program (UGDP). This report has been the subject of intense controversy since its conclusions were made known both because of the unprofessional manner in which the conclusions originally became known, in the lay press, as well as the irreparable flaws of its methodology, and the major inconsistencies in the conclusions. The report, which suggested that tolbutamide is no more effective than diet alone in the treatment of mild adult-onset diabetes, is insupportable in the light of impartial scientific inquiry, and the Food and Drug Administration, by embracing its

conclusions, has intruded into the practice of medicine, placing the physician who continues to prescribe tolbutamide for the treatment of maturity-onset diabetes in jeopardy and causing great concern on the part of more than a million diabetics and their physicians who have regularly used this drug.

This petition is grounded in three fundamental principles:

1. Regardless of the validity of the UGDP study, it is the contention of your petitioners that the Food and Drug Administration's legal mandate is solely the regulation of drugs as to safety and efficacy and not the control of medical or scientific practices; furthermore, the FDA should not engage in the establishment of an official governmental policy in respect to the practice of science or medicine. We believe this to be as true for the treatment of diabetes as it would be in relation to such procedure as cardiac surgery or kidney and heart transplants.

2. The government should particularly refrain from taking a partisan position and establishing a "government line" in an area of medicine and science in which extensive controversy and debate exists among qualified scientists and/or physicians. In the present situation such a position has been taken despite the absence of corroborating studies which have reproduced the UGDP findings, an essential criteria in the establishment of scientific principles. Even if the UGDP study were beyond reproach, which the statement marked "Appendix D" will show it is not, the FDA should not adopt the singular position of one group if contradicting positions are advocated by other qualified scientists and physicians. With respect to the UGDP findings, strong controverting data and extensive comment, disagreement and experience among a large body of

extremely well qualified scientists exists and is a matter of scientific record. Furthermore, in this situation the FDA has ruptured its own rule of fair balance in failing to present the other side of the issue in its mailings and statements, even as it has itself taken sides in the issue.

3. The single study upon which the FDA bases its action has been criticized on professional, scientific, clinical, statistical, and other grounds. Furthermore, FDA action did *not* properly reflect the criticisms and recommendations of its own medical advisory panel on the subject. In effect, despite repeated requests for over a period of a year from many different sources, the basic data of the study remain unavailable to the scientific community and the recent report on phenformin¹ presents an inadequate amount of protocol material to enable adequate scientific evaluation. The 6/23/1971 FDA Current Information Bulletin nevertheless made the general statement that "although this study considered only one sulfonylurea, tolbutamide, it raises serious questions as to the ultimate place of all antidiabetic agents in the treatment of diabetes mellitus."

This petition for a reversal and clarification of the FDA's positions as stated above is thus grounded not only on the basis of the fundamental principle of the separation of science and state, but also on the fact that legitimate scientific controversy exists and the UGDP study has been controverted by a large and leading body of specialists in the field as being more than just erroneous. In point of fact, the FDA has sought in this situation to regulate therapy on the basis of an experiment which is based on

¹ "Effects of hypoglycemic agents on vascular complications in patients with adult-onset diabetes," JAMA, August 9, 1971.

faulty methodology, which has disregarded many essential recommendations related to the true *therapeutic* application of the agents under study, and in doing so has extrapolated without valid statistical basis, thus flying directly in the face of the caveat of the authors of the UGDP study themselves, to wit:

It should be noted that any conclusion reached in this study pertains only to the type of patient studied and to the specific hypoglycemic agents and dosage schedules used. Extrapolation of findings obtained in the UGDP to other dosage schedules of the same drug or to other chemically related hypoglycemic agents not included in this study must be made on a judgmental and nonstatistical basis.²

In addition, it was recently reported that Dr. Christian R. Klimt, the statistical coordinator of the UGDP study, stated that a similar trial of diabetic oral agents, which he will be conducting in Yugoslavia under FDA auspices, will employ a flexible dosage regimen and be confined to a symptomatic diabetic population.³ The use of fixed dosage and asymptomatic patients are two of the serious limiting factors in the UGDP study (see Appendix D). This action by the statistical coordinator indicates the merit of the most serious criticism which has been levelled at the UGDP report.

It has also been reported that the protocol in regard to the double blind technique may not have been followed in every participating clinic for all patients (see Appendix D, Part 2).

² "University Group Diabetes Program," *Diabetes* 19, Supp. 2, 1970.

³ Drug Trade News, August 23, 1971.

Lastly, it should be noted that the conclusions of the study have been specifically rejected by the Canadian Food and Drug Directorate, the Canadian Diabetes Association, the British Committee on Drug Safety, the British Diabetes Association, the German Ministry of Health, the German Diabetic Society, and the Swedish government.

Failure to grant petitioner's requests will result in a continuance and aggravation of damage which has already been perpetrated by the dissemination of these recommendations already made and the suggested labelling changes. As a result of actions taken by the Food and Drug Administration, an undetermined number of patients stopped taking medication on their own or were taken off the medication by their alarmed physicians and subsequently became symptomatic.

Failure to grant these requests will cause further irreparable harm to more than a million patients, particularly to their relationship with their physicians and to their personal psychic stability so essential in a disease such as diabetes.

Failure to grant the request will perpetuate the unjustified damage done to a large number of physicians and research scientists in the field of diabetes with respect to their standing in the public view as well as in the medical and scientific communities.

The Food and Drug Administration has taken a partisan position in an area of valid and continuing medical and scientific discussion and debate. This is a serious error both in principle and in fact. The Food and Drug Administration identification with a controversial study which has been subject to extensive criticism is particularly unfortunate.

It must clearly be recognized that the government has no role as a partisan in valid continuing scientific controversy.

Your petitioners, in reliance on the statement contained in Appendix D of this petition, respectfully request that the following steps be taken immediately:

(1) That the recommendations contained in the October 1970 Food and Drug Administration Current Drug Information Bulletin, entitled "Diabetes Prescribing Information" be immediately rescinded and that notice of such rescission be distributed in exactly the same manner as the Bulletin was distributed.

(2) That the recommendations which would change the INDICATIONS AND WARNINGS section of the labelling of all sulfonylure as stated in the June 23, 1971 Food and Drug Administration Drug Bulletin be rescinded and that notice of same be distributed in exactly the same manner as the Bulletin was distributed.

(3) That the Food and Drug Administration use its best efforts to restore the confidence of patients in their physicians who use tolbutamide and the sulfonylureas generally.

(4) That pending corroboratory studies the Food and Drug Administration refrain from making any further recommendations related to hypoglycemic substances based on the University Group Diabetes Program and that any actions related to the UGDP studies avoid debatable extrapolations and clearly indicate the study's deficiencies and the controversial nature of its implications. And that any references be made in the context of fair balance as above stated.

(5) That the Food and Drug Administration repudiate all other recommendations, statements, mailings or communications of any kind which have been distributed to the medical and scientific communities, to the lay press, or to the general public based on the UGDP study and that the Food and Drug Administration use its best efforts to widely disseminate such repudiation.

(6) That the Food and Drug Administration make available to your petitioners and other qualified researchers the baseline data of the University Group Diabetes Program; such baseline data shall include the total patient record of each patient included in the study.

(7) That in accord with its policy of fair balance, the Food and Drug Administration disseminate with equal effort, emphasis and frequency, the results of all other studies reported by qualified researchers as well as clinical opinions of outstanding diabetologists which disagree with or controvert UGDP study and the conclusions extrapolated therefrom.

(8) That your petitioners be provided with full and complete answers to the following questions:

(a) By virtue of what statute, regulation, rule, or other legal authority does the Food and Drug Administration establish therapeutic regimens by stating preferences —i.e., first, diet; second, insulin and third, oral agents—in its Bulletins marked Appendix A and Appendix B of this petition?

(b) Why did the Food and Drug Administration ignore the views of the majority of its own Advisory Committee on Diabetes, a committee that was composed of four diabetologists, two biostatisticians and a biochemist? That majority was not willing to accept the conclusions of the UGDP report.

(9) That any other relief be granted that the Food and Drug Administration may deem meet and proper to fulfill the spirit and letter of this petition.

respectfully submitted,

Coordinating Committee
of the
Committee on the Care
of the Diabetic

By:

- /s/ ROBERT F. BRADLEY, M.D.
Robert F. Bradley, M.D.
Medical Director
Joslin Clinic
Boston, Massachusetts
- /s/ HENRY DOLGER, M.D.
Henry Dolger, M.D.
Professor of Clinical Medicine
Mount Sinai School of Medicine
City University of New York
New York, New York 10029
- /s/ PETER H. FORSHAM, M.D.
Chief of Endocrinology
Professor, Department of Medicine
University of California Medical Center
San Francisco, California 94122
- /s/ HOLBROOKE S. SELTZER, M.D.
Holbrooke S. Seltzer, M.D.
Chief of Endocrinology
Professor of Internal Medicine
Veterans Administration Hospital
University of Texas
Southwestern Medical School
Dallas, Texas 75235
- /s/ NEIL L. CHAYET, Esq.
Neil L. Chayet, Esq.
Attorney for the Committee
15 Court Square
Boston, Massachusetts 02108

EXHIBIT B

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

No. 73-1014

ROBERT F. BRADLEY, et al.,
Plaintiffs, Appellees,

v.

CASPAR W. WEINBERGER, SECRETARY OF
HEALTH, EDUCATION AND WELFARE, et al.,
Defendants, Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

*Before COFFIN, Chief Judge,
ALDRICH and McENTEE, Circuit Judges.*

William A. Brown, Assistant United States Attorney, with whom *James N. Gabriel*, United States Attorney, *Thomas E. Kauper*, Assistant Attorney General, Anti-Trust Division, *George Edelstein*, Attorney, Department of Justice, *Peter Barton Hunt*, Assistant General Counsel, *Joanne S. Sisik*, Chief, Appellate and Special proceedings Branch, and *Arthur N. Levine*, Attorney, Food, Drugs and Product Safety Division, were on brief, for appellant.

Neil L. Chayet, with whom *Harvey W. Freishtat* and *Chayet* and *Sonnenreich* were on brief for Robert F. Bradley, et al, plaintiffs, appellees.

July 31, 1973

COFFIN, Chief Judge. Plaintiffs, 178 physicians who treat diabetes and one diabetes patient who use oral hypoglycemic agents to control the disease by lowering the blood sugar level, brought suit to enjoin the defendants Secretary of

Health, Education and Welfare and the Commissioner of the Food and Drug Administration (FDA) from enforcing and the defendant drug companies from complying with the FDA's proposal for altering the labeling of those drugs. The district court granted a preliminary injunction, being persuaded that there was a reasonable likelihood of success in showing that the FDA had failed to comply with the statutes and its own regulation requiring that under some circumstances labeling make reference to the existence of a serious medical controversy. We vacate the injunction for reasons important to the proper judicial role in reviewing administrative actions.

This controversy revolves around a long-term, federally funded study undertaken by the University Group Diabetes Program (hereafter the UGDP study) to determine the effects of oral hypoglycemic agents on vascular complications in patients with adult-onset diabetes. The study, involving twelve clinics and 1200 patients, consisted of four treatment groups: diet alone, diet plus regular insulin doses, diet plus varying insulin doses and diet plus fixed doses of either tolbutamide or phenformin (two hypoglycemic agents). After monitoring the patients for from five to eight years, the study concluded that the combination of diet and either tolbutamide or phenformin was no more effective than diet alone in prolonging life but that those oral agents might be more hazardous than diet or diet plus insulin insofar as cardiovascular mortality was concerned. The latter conclusion, which led the investigators to discontinue use of the agents in the study as an unethical risk, was based on findings that patients treated with the two agents used in the study suffered more than twice as many cardiovascular deaths and patients receiving the other treatments.

After the study received much publicity and criticism, the FDA convened an ad hoc committee of experts on May 21, 1970 to evaluate the study's findings and the following

day issued a press release agreeing with the UGDP study's conclusions and indicating that the agency would require labeling changes to reflect those views. After more extensive evaluation, the FDA concluded that protection of the public required a strong warning to physicians recommending use of an oral agent only if other treatments were inadvisable and noting that UGDP's findings regarding the apparently increased danger of cardiovascular mortality. This evaluation and proposed labeling change was first formally published in the *FDA Drug Bulletin* of June, 1971.

On October 7, 1971, the Committee on the Care of the Diabetic, consisting of eminent doctors and experts in the field including some of the plaintiff doctors, submitted through its counsel a petition to the FDA. It asked the FDA to rescind its labeling recommendation, insure that all future FDA comments on the UGDP study include references to its alleged deficiencies and controversial nature, provide petitioners with the complete raw data of the study, and, "in accord with its policy of fair balance", disseminate with equal emphasis and frequency studies and individual expert opinions differing with the study. The petition was accompanied by a detailed scientific critique of the UGDP study and some 250 pages of scientific studies, papers and comments illustrating the nature and extent of the opposition viewpoint. The study was primarily criticized for inadequate patient selection controls and use of fixed, rather than variable, doses of the drugs, contrary to allegedly accepted medical practice. The FDA proposal was attacked for extending the study's findings to all oral agents and patients despite the study's own warning that such extrapolation could not be made on a statistical basis. The petition also referred to two smaller studies which indicated no cardiovascular complications from oral agents. It was supplemented in January, 1972, by another 220 pages of scientific materials.

In the May, 1972, *Drug Bulletin*, the FDA published the "Final Labeling Approved For Oral Hypoglycemic Drugs", which proposed changes in the "indications" section of the label and the addition of a "special warning" section. The proposal speaks of "the increased cardiovascular hazard which appears to be associated with oral hypoglycemic agents", notes that the UGDP study was the basis for the change, recites its findings, states that these conclusions apply to all oral agents, not just those employed in the study, and ends with the comment that "Further studies are being undertaken to shed additional light on the role" of the oral agents. On June 5, 1972, the Commissioner formally replied to the Committee's position with an eleven-page, single-space letter addressing generally the legal and medical issues and with a 100 page appendix dealing specifically with the scientific criticisms of the study, criticizing the two contrary studies referred to by the petition, and appending the comments of major medical groups and various scientific papers supportive of the FDA's position. The Committee's counsel responded on July 13 with a four-page letter suggesting that the FDA's label might constitute misbranding in violation of two cited statutes, that this was one of the "rare cases" suggested by the Commissioner in which "substantial evidence" exists on both sides of an issue, making appropriate reflection of the controversy in the package insert. Counsel requested a formal evidentiary hearing, a stay of any further action pending final resolution, and the full patient records from the study. The Commissioner's response of August 3 stated that the petitioners were not entitled to a hearing and that only clinical studies were substantial evidence of drug effectiveness. He concluded by saying that, "we do not contend that you do not have standing either to prosecute your petition [sic] or to pursue an appeal to the courts" and that his two letters constituted final agency action reviewable by the courts pursuant to the Administrative Procedure Act.

This suit was filed on August 11, 1972 and a temporary restraining order issued that day. After a hearing and submission of affidavits of experts by both sides, the emergency district judge denied the preliminary injunction on August 30, finding that whatever irreparable injury might be suffered by the plaintiffs did not outweigh that suffered by the public represented by the defendants and that the plaintiffs had not demonstrated "a reasonable probability" of showing that the FDA's decision to require the warning was arbitrary or capricious. A second motion for a preliminary injunction was denied on September 21 by the judge to whom the case was permanently assigned because no new evidence or amendment of the complaint had been presented.

On October 17, 1972, the litigation entered an entirely new phase. On that date, plaintiffs filed a motion for leave to amend their complaint, supported by 13 affidavits by diabetes experts attesting to the controversy over the UGDP study, and new motions for a temporary restraining order and a preliminary injunction. The motions presented for the first time the argument that the FDA's proposed label was itself misleading and thus rendered the drug misbranded in violation of the statute, because it failed to reveal the existence of a "material weight of contrary opinion" among "experts qualified by scientific training and experience" as allegedly required by the agency's own regulation, 21 C.F.R. §1.3. After oral argument, at which plaintiffs' counsel admitted this was an unprecedented case, being brought by the doctors and seeking to apply that regulation to the agency's own labeling recommendation, the district court in a Memorandum and Order granted on November 3, 1972, the motions to amend the complaint and for a preliminary injunction. It noted that "The application for preliminary injunction was heard on the affidavits filed by plaintiffs and defendants, and their arguments both oral and written" and stated that "the court is satisfied plaintiffs have

made a showing that there is reasonable likelihood upon a full hearing on the merits they would be successful in establishing the defendants . . . have not in the order described in the May 1972 Bulletin complied with 21 C.F.R. § 1.3.; 21 U.S.C. § 321(n) and 21 U.S.C. § 352(a).", and that "there is [absent an injunction] a likelihood of irreparable injury to the plaintiffs" greater than would be visited upon the defendants by such relief.

The district court had jurisdiction to review the administrative action under the Administrative Procedure Act (APA), 5 U.S.C. § 704, because it was "final agency action for which there is no other adequate remedy in a court." See *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967); *Weinberger v. Hynson, Wescott & Dunning, Inc.*, 41 U.S.L.W. 4848, 4853 (U.S. June 18, 1973).¹ There is no dispute

¹ The right to petition the court of appeals for review under 21 U.S.C. § 355(h) is available only to a drug-marketing applicant after an order refusing or withdrawing approval of a drug application. Although the FDA has no direct statutory power to compel labeling changes, it may refuse or withdraw approval of an application, under § 355(d) or (e), if new information demonstrates that the labeling is "false or misleading." Since the drug companies here were willing to amend their labels in accordance with the FDA proposal, no withdrawal procedures were ever begun and thus the agency action was final in a meaningful sense. *Abbott, supra*.

Before this court, the government, for the first time, argued that plaintiffs did not have standing to sue, not being persons "adversely affected or aggrieved by agency action within the meaning of a relevant statute" as required by 5 U.S.C. § 702. Even assuming that the government may still raise this claim notwithstanding an explicit concession of standing by the specialized agency charged with interpretation and enforcement of the relevant statute, the case is properly before us. While there might be some doubt whether the plaintiff doctors, who clearly alleged "injury in fact", *Sierra Club v. Morton*, 405 U.S. 727 (1972); *United States v. Students Challenging Regulatory Agency Procedures*, 41 U.S.L.W. 4866 (U.S. June 18, 1973), because of the impact of the label changes on their

over the scope of review—whether the agency action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).² The action challenged was informal agency action, subject to judicial review under that standard.³ *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971); *Camp v. Pitts*, 41 U.S.L.W. 3515 (U.S. Mar. 26, 1973).

Significantly, there is also no controversy over the basis for judicial review—"the full administrative record that was before the [Commissioner] at the time he made his decision." *Overton Park, supra*, 401 U.S. at 420.⁴ Yet, as

medical practice and on malpractice suits, have an interest "arguably within the zone of interests to be protected or regulated", *Data Processing Service v. Camp*, 397 U.S. 150 (1969), there can be no question that the plaintiff patient's interest is in the very center of that zone.

² While the plaintiffs now also contend that the agency's failure to follow its own regulations is a violation of due process, thus apparently also invoking the review standard of § 706(2)(B), "contrary to constitutional right, power, privilege, or immunity", that approach would change neither the nature of the review nor the result. If an agency action violates a regulation, it is "not in accordance with law" as well as violative of due process, *United States v. Griglio*, 467 F.2d 572 (1st Cir. 1972). Moreover, courts must review agency actions under both standards in all cases. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971). If, however, a regulation has been violated, there would seldom be occasion to decide the constitutional issue.

³ Plaintiffs do not now claim that they are entitled to an evidentiary administrative hearing.

⁴ The plaintiffs insist that the record must include not only their petition and the Commissioner's response, which the record before us contains, but also the original patient records of the UGDP study, any intra-agency and other memoranda, factual reports and scientific studies before the Commissioner, and the minutes taken during the deliberations of the ad hoc advisory committee convened by the FDA the day before its first press release regarding the study. While in light of our discussion we need not resolve the

the district court's brief memorandum indicates, the preliminary injunction was based not on a review of that record but on the affidavits presented by both sides to the court. As the Supreme Court has only recently reiterated, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, *supra*, 41 U.S.L.W. at 3515. There are strong policy reasons behind this requirement. Litigation affidavits are often "merely 'post hoc' rationalizations . . . which have traditionally been found to be an inadequate basis for review." *Overton Park*, *supra*, 401 U.S. at 419; *see Trailways of New England, Inc. v. C.A.B.*, 412 F.2d 926, 931 (1st Cir. 1969). Moreover, this rule is significant in limiting courts to their proper role. Courts are to determine whether an agency's action was arbitrary or capricious in light of the information it confronted. It is a re-view, a second look at the same material, not a re-doing. And, of course, limiting review to the existing administrative record also saves judicial time.

The requirement that review be on the administrative record parallels and supports the exhaustion of administrative remedies doctrine which reflects similar policies. To the extent that the record reflects consideration of arguments made and evidence submitted, it also reflects the focus which the agency had in bringing to bear its expertise. The exhaustion requirement, as it applies to administrative agencies, is no mere technical rule to enable courts to avoid difficult decisions. It is grounded in substantial

propriety of each of these requests, we reiterate what we recently stated in an analogous situation: "We think the law requires production of the entire administrative record While there may be some instances in which the entire record need not be filed, where the correctness of factual findings are involved or where the complainants request the full record, we think the agency must produce it in court. *Cf.* 28 U.S.C. § 2112(b)." *Silva v. Romney*, No. 73-1200 (1st Cir. July 5, 1973) (slip op. at 3 & n. 1).

concerns not only of fairness and orderly procedure, *N.L.R.B. v. Rexall Chemical Co.*, 370 F.2d 363, 365-66 (1st Cir. 1967); *United States v. Tucker Truck Lines, Inc.*, 344 U.S. 33, 36-37 (1952), but also of competence. Courts are not best equipped, as both sides here readily agree, to judge the merits of the scientific studies and the objections to them. Specialized agencies like the FDA are created to serve that function. In this case, the regulation which, in their motion to amend, plaintiffs contend specifically governs the content of a balanced label, 21 C.F.R. § 1.3, was never presented to the Commissioner nor referred to in the administrative record. It is the significance of this omission that governs our disposition.

Plaintiffs argue that while this regulation was never mentioned in the administrative proceedings, the concept of "fair balance" which it represents was fully presented and argued by them in their initial petition, was explicitly rejected by the Commissioner in his initial letter, and that the specific statutes under which this regulation was promulgated were mentioned in plaintiffs' letter of response. While we recognize that the concept was put forward, are fully aware of the disadvantages of further delay, and do not wish to render the exhaustion doctrine a rigid and technical barrier, several factors in this case lead us to insist that the specific argument now pressed be first thrashed out in the administrative arena.

Most significantly, this is an unprecedented argument. As plaintiffs' counsel readily admitted in oral argument before the district court, there appears to be no prior case in which an FDA drug labeling decision was challenged not by the producer but by concerned medical practitioners, and no case in which the misbranding statutes and regulations were sought to be applied not to the manufacturer's label but to the FDA's proposal for alteration of the label in light of new information. It is thus not surprising that the dialogue that did occur regarding "fair balance" was

on an entirely different plane. The Food, Drug and Cosmetic Act as amended in 1962 requires that applicants seeking approval for marketing of new drugs present "substantial evidence" of the drug's effectiveness as well as evidence of its safety. The term "substantial evidence" is defined in the statute to mean "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved". 21 U.S.C. § 355(d). The FDA has promulgated a detailed regulation to further refine and clarify that definition. 21 C.F.R. § 130.12. *See Hynson, supra*. Yet the statute provides that approval of an application may be refused or withdrawn not only because "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have", 21 U.S.C. §§ 355(d)(5), (e)(3), or there is "insufficient information to determine whether such drug is safe", § 355(d)(4), *see also* § 355(e)(2), but also if "based on a fair evaluation of all material facts", the drug's labeling is "false or misleading in any particular." §§ 355(d)(6), e(4) (second sentence).

The Commissioner, in his ruling on plaintiffs' petition, rejected the argument for "fair balance" because he said that Congress had determined in 1962 that "unsubstantiated expert opinion could no longer suffice to establish the effectiveness of drugs", and that "Except perhaps in rare instances where there is substantial evidence on both sides of an issue, therefore, it is inappropriate to utilize the package insert to present all aspects of the evidence relating to safety and effectiveness." Since he found that not the situation here, he saw "no basis" for a balanced label. Plaintiffs' reply, although noting the possibility that the FDA's proposal might constitute misbranding under the relevant statutes, *see infra*, primarily argued that "this is in fact one of those rare instances" in which "substantial evidence" exists on both sides of an issue and thus, as the Commissioner's letter suggested, warranted balanced labeling treatment. The Commissioner's reply was that the plaintiffs had

not in fact presented "substantial evidence" as defined by Congress.

Now, aware of the stringency of the substantial evidence test, *see Hynson, supra*, the plaintiffs argue that the misbranding statutes and regulation apply. Section 502 of the statute, 21 U.S.C. § 352, declares that "A drug . . . shall be deemed to be misbranded—(a) if its labeling is false or misleading in any particular." The definitional statute (21 U.S.C. § 321(n)) provides: "If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading, there shall be taken into account (among other things) not only representations made or suggested . . . but also the extent to which the labeling fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates." Implementing the latter definition is regulation 1.3:

"The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation."

One reading of this regulation would suggest that unsubstantiated individual clinical opinions of qualified experts, which are insufficient under the "substantial evidence" test enacted in the effectiveness section, might be sufficient to create a fact omission of which might render the labeling misleading.

The Commissioner never considered the meaning of this regulation, its relationship to the substantial evidence test, the intersection of the safety, effectiveness, and misbranding requirements, or the applicability of the misbranding requirements, both statutory and regulatory, to an FDA

proposal for re-labeling, for the simple reason that the issue was not presented to him.⁵ Arguably these are simply issues of law which we are fully capable of resolving without administrative assistance. But as the Supreme Court has very recently noted in similarly resolving a closely analogous case, the interpretation of even definitional sections in the drug law will often involve expert knowledge and the ability to evaluate the scientific evidence that becomes relevant. *Weinberger v. Bentex Pharmaceuticals, Inc.*, 41 U.S.L.W. 4858, 4860-61 (U.S. June 18, 1973). Moreover, we have here not only novel issues concerning the interpretation of the statute, which the specialized enforcement agency should first undertake, but also unprecedented inquiries as to the meaning of the agency's own regulations. It is thus no answer to say that an agency need not be reminded of its own regulations. Finally, both the definitional statute and its implementing regulation on which the district court relied explicitly anticipate the exercise of administrative discretion, since they require only that the omission of expert differences of opinion be considered, along with all other relevant facts, in determining whether a label is misleading. As the Court recently reaffirmed: "uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure." *Bentex, supra* at 4861.

An equally important reason for insisting on exhaustion here is that insofar as the record reveals the administrative

⁵ Similarly he never considered the applicability or meaning of 21 C.F.R. § 1.106(b)(3)(i), which plaintiffs refer to as the "full disclosure" regulation, but which they failed to disclose not only to the Commissioner but to the district court. Obviously, the relevance and impact of that regulation should also first be presented for administrative consideration.

process seems to have been working well in this instance. The initial ad hoc advisory committee convened by the agency included several eminent critics of the UGDP study, indeed some of the plaintiffs here. While the response to Dr. Bradley's initial communications may not have been fully satisfactory, the response to the Committee's petition was both lengthy, detailed, and technical. Even the rebuttal letter, essentially in the form of a petition for reconsideration, a useful procedure in insuring that objections to even the supposedly final agency decision are first brought to its attention, received a specific and complete response. Arguments, studies, and materials, were not ignored; difficult problems were not swept under the rug. The communications evidenced agency recognition of the plaintiffs' expert status, and, as the concession of standing indicates, receptivity to criticism. Additionally, we were informed at oral argument that extensive negotiations between the parties to arrive at a mutually acceptable solution to the labeling problem had been carried on during much of this litigation. We thus have more than a pious hope that a remand to the agency will not only not be futile, but could well produce the most informed and responsible solution possible.

Because the plaintiffs failed to exhaust their administrative remedies regarding the issues they now present and, consequently, the district court reviewed the agency decision on something other than the administrative record, we must vacate the injunction.⁶

Injunction vacated; case remanded for further proceedings consistent with this opinion.

⁶ We therefore need not decide whether reversal would have been required, as argued by the defendants, because the district court, in granting the injunction, did not, as required by Fed. R. Civ. P. 52(a), "set forth the findings of fact and conclusions of law which constitute the grounds of its action". While the context will often render obvious the grounds of decision, district courts should generally follow the rule's mandate to obviate any possibility of misunderstanding, unnecessary reversal and/or delay.

EXHIBIT C

WESTERN UNION MAILGRAM

CHAYET AND SONNENREICH
6 FAYETTE ST
BOSTON MA 02109

RECEIVED OCT. 16, 1974, NEIL L. CHAYET

THIS MAILGRAM IS A CONFIRMATION OF THE FOLLOW-
ING MESSAGE:

6173570204 TDHT BOSTON MA 82 10-15 0710P EDT

PHS G DONNARD WHEEDON DIRECTOR MEGABOLIC
SERVICES NATIONAL INSTITUTE OF HEALTH, FONE:
DLR
BETHESDA MD

HAS BEEN INFORMED THAT A DRAFT BIOMETRIC
STUDY IS AVAILABLE AND HAS BEEN CIRCULATED
FOR REVIEW AND COMMENT. I AM REQUESTING COPY
OF THIS REPORT BE IMMEDIATELY MADE AVAILABLE
TO REPRESENTATIVE OF THE COMMITTEE AND THE
CARE OF THE DIABETIC. ALSO REQUEST THAT ACCESS
TO THE RAW DATA WHICH WAS ACCORDED TO THE
BIOMETRIC STUDY BE SIMILARLY AND IMMEDIATELY
MADE AVAILABLE TO REPRESENTATIVE OF THE COM-
MITTEE AND THE CARE OF THE DIABETIC. YOUR UR-
GENT REPLY TO THIS REQUEST IS AWAITED.

NEIL L CHAYET COUNSEL AND SONNENREICH 6 FA-
YETTE ST BOSTON MA

19:10 EDT

HGHBSNT HSB

EXHIBIT D

WESTERN UNION TELEGRAM

BBD221(1443)(1-0238180291)PD 10/18/74 1441

TLX HEWNIH BHDA C

ZCZC 1 NL PD BETHESDA MD OCT 18

PMS NEIL L CHAYET COUNSEL

CHAYET AND SONNENREICH

6 FAYETTE STREET

BOSTON MASSACHUSETTS 02116

RECEIVED OCT. 23, 1974,
CHAYET AND SONNENREICH, P.C.

PRELIMINARY DRAFT OF REPORT OF BIOMETRICS SO-
CIETY HAS BEEN PROVIDED TO ME FOR MY INFOR-
MATION AS HEAD OF THE CONTRACTING AGENCY FOR
THIS REPORT AND HAS NEVER BEEN CIRCULATED FOR
REVIEW AND COMMENT. FINAL DRAFT WILL NOT BE
CIRCULATED FOR REVIEW AND COMMENT BUT WILL
BE PUBLISHED IN THE JOURNAL OF AMERICAN MEDI-
CAL ASSOCIATION.

DR G DONALD WHEDON, DIRECTOR

NIAMDD NIH

EXHIBIT E

CHAYET AND SONNENREICH, P.C.

Attorneys at Law

Watergate 600, Suite 720

600 New Hampshire Avenue, Northwest

Washington, D.C. 20037

(202) 965-4150

November 4, 1974

Mr. Peter Hutt
 Assistant General Counsel
 Food and Drug Division
 Food and Drug Administration
 Department of Health, Education and Welfare
 Office of the Secretary
 5600 Fishers Lane
 Rockville, Maryland 20852

Dear Peter:

Enclosed you will see the telegram I sent to Dr. G. Donald Wheeden on October 15, 1974 and his reply to me of October 21, 1974. You will note that the reply is not responsive to the request I made.

Since the Biometric Society study has been circulated for review and comment, I thought it only fair that the Committee for the Care of the Diabetic be allowed to see such study and to comment upon it. I also feel it is essential that the Committee have available the raw data which was given to the Biometric Society so that we might see the basis upon which the study founded its conclusions and recommendations.

I wish to formally make the request, on behalf of the Committee, for both a copy of the currently circulated draft and for access to the raw data upon which the draft was

based. It is my belief that this material is lawfully available to the Committee as an interested party under the Freedom of Information Act and on the basis that these documents and data have been circulated to other interested persons for review and comment.

I look forward to your early reply on this most urgent matter.

Yours truly,

/s/ NEIL L. CHAYET
 Neil L. Chayet

EXHIBIT F

Attachment 5

DEPARTMENT OF HEALTH, EDUCATION, AND
WELFARE

Office of the Secretary

Rockville, Md. 20852

November 11, 1974

Received Nov. 15, 1974, Chayet and Sonnenreich, P.C.

Neil L. Chayet, Esq.
 Chayet and Sonnenreich, P.C.
 Six Fayette Street
 Boston, Massachusetts 02116

Dear Mr. Chayet:

This is in response to your letter of November 4, 1974, requesting a copy of the current draft of the Biometric Society and access to the raw data given to the Society upon which the Society has drafted its conclusions and recommendations.

This is to advise you that the Food and Drug Administration does not have a copy of a draft report, and we have no information whatever about it being circulated for review and comment. As I have previously advised you, both the UGDP study and the Biometric Society study were funded by NIH, not by FDA, and we have had no connection with the report or the material sent to the Biometric Society committee for their review.

I am forwarding your letter to Sidney Edelman, Esq., Assistant General Counsel for the Public Health Division

and thus for NIH, with the request that he pursue the matter further.

Sincerely yours,

/s/ PETER BARTON HUTT
 Peter Barton Hutt
 Assistant General Counsel
 Food and Drug Division

cc: Sidney Edelman, Esq.

EXHIBIT G

DEPARTMENT OF HEALTH, EDUCATION, AND
WELFAREOffice of the Secretary
Washington, D.C. 20201

November 22, 1974

Received Nov. 25, 1974, Chayet and Sonnenreich, P.C.

Neil L. Chayet, Esq.
Chayet and Sonnenreich, P.C.
Six Fayette Street
Boston, Massachusetts 02116

Dear Mr. Chayet:

Reference is made to your letter of November 4, 1974 requesting a copy of a draft Biometric Society study and the raw data on which the study was based.

Inasmuch as any such materials would be in the files of the National Institute of Arthritis, Metabolism, and Digestive Diseases, we have referred your letter to that Institute for reply.

Sincerely yours,

/s/ SIDNEY EDELMAN
Sidney Edelman
Assistant General Counsel
for Public Health

EXHIBIT H

DEPARTMENT OF HEALTH, EDUCATION, AND
WELFAREOffice of the Secretary
Washington, D.C. 20201

December 3, 1974

Received Dec. 6, 1974, Chayet and Sonnenreich, P.C.

Mr. Neil L. Chayet, Esq.
Chayet and Sonnenreich, P.C.
Six Fayette Street
Boston, Massachusetts 02116

Dear Mr. Chayet:

Further reference is made to the exchange of telegrams between you and Dr. G. Donald Wheden, Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases, NIH, and correspondence dated November 4 and 11 between you and Mr. Peter Barton Hutt, Assistant General Counsel, Food and Drug Division, FDA. Your request was referred to me because of my responsibilities under the Freedom of Information Act.

In your letter and telegram you asked for a draft of a report of a review by the Biometrics Society of a long term study of the safety and effectiveness of oral drugs in diabetes. The Biometrics Society review was contracted for by the National Institute of Arthritis, Metabolism, and Digestive Diseases.

The Department's policy calls for the fullest possible disclosure of records consistent with the requirements of administrative necessities and confidentiality recognized by the Freedom of Information Act. Copies of the Act (5

U.S.C. 552) and the Department's implementing Public Information Regulation (45 CFR, Part 5) are enclosed for your information. Included in records available section 5.72 (e), you will note: "The final report of a grantee or a contractor of the performance under any research, development, or demonstration project records, other than reports, produced in such projects, such as films, computer software, other copyrightable material and reports of inventions, will be available, except that considerations relating to obtaining copyright and patent protection may require delay in disclosure for such period as necessary to accomplish such protection.

The material you cite is a preliminary draft, not a final report. Once the final report is completed, the National Institute for Arthritis, Metabolism, and Digestive Diseases will be glad to furnish it promptly to you.

You have the right to appeal this decision within thirty (30) days. Should you wish to do so, the procedure is outlined under Subpart G of the Department's Regulation. Any such appeal should be addressed to the Assistant Secretary for Health, Department of Health, Education, and Welfare, 330 Independence Avenue, S.W., Washington, D.C. 20201.

Sincerely yours,

/s/ RUSSELL M. ROBERTS
Russell M. Roberts
Freedom of Information Officer
Office of Public Affairs

Enclosure

EXHIBIT I

CHAYET AND SONNENREICH, P.C.

Attorneys at Law

6 Fayette Street

Boston, Massachusetts 02116

(617) 357-0202

January 2, 1975

Dr. Charles C. Edwards
Assistant Secretary for Health
Department of Health, Education, and Welfare
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Edwards:

This is to request review of the denial on December 3, 1974 of my requests on behalf of the Committee on the Care of the Diabetic (CCD) for a copy of the draft of the Biometrics Society report on the University Group Diabetes Program (UGDP) and for access to the raw data on which the report is based (Attachment 1).

These materials were earlier requested through an exchange of telegrams with Dr. G. Donald Whedon, Director of the National Institutes of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health, in October 1974 (Attachments 2 and 3) and an exchange of correspondence with Mr. Peter Barton Hutt, Assistant General Counsel, Food and Drug Division, Food and Drug Administration, in November 1974 (Attachments 4 and 5).

The basis for the request is my belief that such materials constitute "identifiable records" of an agency lawfully available to the public under the Freedom of Information Act (5 USC § 552). In establishing a general policy of disclosure rather than secrecy, the FOIA requires government

agencies to make available to the public a broad range of information that is not specifically exempted, with the burden of justifying non-disclosure placed on the agency and with any cited exemption to be narrowly viewed.

Neither the letter of December 3 nor any FOIA law or regulation restricts CCD's access to the raw data on which the UGDP and the Biometrics studies are based. Accordingly, CCD assumes that access to such data is to be provided.

With respect to the Biometrics study, the denial of December 3 was purportedly based on 45 CFR § 5.72(e) of DHEW's Public Information Regulation. However, as a part of the "records available" section of the Regulation, Section 5.72(e) simply affirms public access to the "final report of a grantee or a contractor . . . under any research . . . project" with certain exceptions not relevant here. Neither 5.72(e) nor any other section of the Regulation discusses, much less restricts, the availability of identifiable records which are not yet "final reports". DHEW's denial is, therefore, apparently premised on a notion that the public can have access only to what is specifically allowed, whereas the FOIA guarantees disclosure of all records not specifically prohibited (5 USC § 552(c)).

Of the nine specific legislative exemptions to full disclosure, however, the only exemption that could even conceivably be invoked to justify the denial of the requested Biometrics study is the fifth

inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency (§ 552 (b)(5)).

In establishing Exemption 5, Congress expressly intended "to delimit the exception as narrowly as consistent with efficient Government operation." S. Rep. No. 813, p. 9. The Exemption has been generally construed to permit government non-disclosure only to the extent necessary to protect

materials reflecting policy-making processes as opposed to factual or investigatory reports. In *Bristol Myers Co. v. FTC* 424 F. 2d 935, cert. denied 400 U.S. 824 (1970), the distinction was explained as follows:

Purely factual reports and scientific studies cannot be cloaked in secrecy by an exemption designed to protect only "those internal working papers in which opinions are expressed and policies formula and recommended" at 939 quoting *Ackerly v. Ley*, 420 F. 2d 1336, 1341 (1969)).

The Biometrics study, conducted over the past 18 months by a special panel of the Society at a cost of \$80,000, has been charged to investigate the systems of data evaluation adopted by the UGDP and to determine their acceptability according to objective biostatistical standards. The panel was not intended to delve into the realm of policy; rather, its report was to provide the purely factual predicate upon which DHEW policy could then be made.

DHEW's promulgation of 5.72(e) attests to the limited scope of Exemption 5 by guaranteeing disclosure of the final report of the Biometrics study. It is all the more unclear, therefore, why a preliminary report of the same study, acknowledged to be in DHEW's possession, should be regarded any differently for purposes of disclosure.

In addition to the FOIA-guaranteed public interest in disclosure, CCD has a particularized interest in disclosure of the documents requested herein. Consisting of approximately 180 eminent diabetologists from around the country, CCD was organized to ensure that any policy-making based on the UGDP study was informed by a broader spectrum of medical and scientific evidence and opinion. It was when FDA indicated its intention to act solely on the basis of the UGDP study and without providing access to the data on which the findings were based that CCD sought the assistance of the Court. *Bradley v. Weinberger* 483 F.2d 410 (1st Cir. 1973).

Particularly relevant for purposes of the request herein is the First Circuit's view of the type of information to which CCD is entitled:

The plaintiffs (CCD) insist that the record must include not only their petition and the Commissioner's response, which the record before us contains, *but also the original patient records of the UGDP study, any intra-agency and other memoranda, factual reports and scientific studies before the Commissioner* and the minutes taken during the deliberations of the ad hoc advisory committee convened by the FDA the day before its first press release regarding the study. While in light of our discussion we need not resolve the propriety of each of these requests, we reiterate what we recently stated in an analogous situation: "We think the law requires production of the entire administrative record . . . While there may be some instances in which the entire record need not be filed where the correctness of factual findings are involved or where the complainants request the full record, we think the agency must produce it in court. [citing cases.] (483 F. 2d 410, at fn. 4) (emphasis supplied).

The First Circuit has thus implicitly reaffirmed the discoverability of the information CCD is requesting. In fact, it was in the hope of full dialogue and disclosure at the administrative level that the Court remanded the matter for additional agency consideration.

In my judgment, denial of the request herein would, therefore, violate not only the provisions of the FOIA but also the express intent of the Court.

Very truly yours,

Neil L. Chayet

Enclosures

DEPARTMENT OF HEALTH, EDUCATION, AND
WELFARE

Office of the Secretary
Washington, D.C. 20201

Received Jan. 17, 1975, Chayet and Sonnenreich, P.C.

Neil L. Chayet, Esq.
Chayet and Sonnenreich, P.C.
Watergate 600, Suite 720
600 New Hampshire Avenue N.W.
Washington, D.C. 20037

Dear Mr. Chayet:

Thank you for your letter of January 7 in which you ask for a review of the denial of your request for a copy of a report of the Biometrics Society on the University Group Diabetes Program.

The facts of this case are currently being reviewed in my office, and I will inform you of the results of my decision in the near future.

Sincerely yours,

/s/ CHARLES C. EDWARDS
Charles C. Edwards, M.D.
Assistant Secretary for Health

EXHIBIT J

DEPARTMENT OF HEALTH, EDUCATION,
AND WELFAREPUBLIC HEALTH SERVICE
NATIONAL INSTITUTE OF HEALTH
BETHESDA, MARYLAND 20014Building 31 Pages 9A 52
Area Code 301-496-5877

January 27, 1975

Neil L. Chayet, Esq.
Chayet and Sonnenreich, P.C.
Watergate 600, Suite 220
629 New Hampshire Avenue, N.W.
Washington, D.C. 20037

Dear Mr. Chayet:

In response to your request transmitted to me recently by Dr. Charles C. Edwards, I am making available to you a copy of the report of the Biometric Society on the University Group Diabetes Program. To my knowledge, no one in the Department of Health, Education and Welfare has ever had any of the raw data of the UGDP study.

Sincerely yours,

/s/ G. DONALD WHEDON, M.D.
G. Donald Whedon, M.D.
Director
National Institutes of Arthritis,
Metabolism, and Digestive Diseases

Enclosure

EXHIBIT K

CHAYET AND SONNENREICH, P. C.
Attorneys at Law6 Fayette Street
Boston, Massachusetts 02116

(617) 357-0202

May 6, 1975

Theodore Cooper, M.D.
Acting Assistant Secretary for Health
Department of Health, Education and Welfare
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Cooper:

This is to renew my appeal of January 7, 1975 from the denial of my requests on behalf of the Committee on the Care of the Diabetic (CCD) for a copy of the draft of the Biometrics Society report on the University Group Diabetics Program (UGDP) and for access to the raw data on which the report is based.

The letter from Dr. Edwards of January 17 was not responsive to my request relative to the raw data.

The response of Dr. G. Donald Whedon on January 27 was similarly unresponsive in that it did not provide the requested preliminary draft of the Biometrics Society report, but rather produced only the galley proofs of the final version as eventually published in the Journal of the American Medical Association. Further, Dr. Whedon did not respond to my request that the CCD be accorded full access to the UGDP raw data or, at the very least, the same access as was accorded the Biometrics Society.

Your review of the denial of the foregoing requests is again requested in accordance with the provisions of the Freedom of Information Act (5 USC § 552) and DHEW's implementing regulations (45 CFR Part 5) as a final attempt to secure relief at the administrative level.

The CCD also requests that the following be made available: The UGDP study research design and protocol submitted with the funded initial grant application, as well as any research designs and protocols submitted with application for continuation, renewal or supplemental grants (including interim progress reports) whether funded or not. In addition, the CCD requests a full statement detailing all budgets, appropriations, actual allocations and expenditures with respect to the UGDP study. This information is sought pursuant to DHEW's regulation with respect to research designs and protocols published in the Federal Register of May 1, 1975 (40 F.R. 18997).

This letter renewing my earlier request is a final attempt to achieve an administrative resolution of this matter.

Very truly yours,

Neil L. Chayet

NLC:jlj

EXHIBIT L

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service
Washington, D.C. 20201

May 23, 1975

Neil L. Chayet, Esq.
Chayet and Sonnenreich, P.C.
6 Fayette Street
Boston, Massachusetts 02116

Dear Mr. Chayet:

Thank you for your letter of May 6 regarding your request for further information in the Biometrics Society report on the University Group Diabetes Program.

I have reviewed this matter and find that Dr. Whedon did respond to your request regarding the raw data on which the UGDP study was based. In his letter of January 27, Dr. Whedon stated that this Department does not now have and never has had any of the raw data on which the UGDP study was based. Given that the data you request are not records belonging to this Department, I have no Freedom of Information Act jurisdiction over them.

Your other previous request was for the draft report of the study. The only draft report which the Department received was the one provided to you, viz. the galley proofs. We have no other drafts.

Your request for the UGDP study research design and protocol is a new request. I have, therefore, transmitted it to the National Institutes of Health for direct reply.

Should you have further questions regarding this matter,
please do not hesitate to contact my office.

Sincerely yours,

/s/ THEODORE COOPER, M.D.
Theodore Cooper, M.D.
Acting Assistant Secretary for Health

EXHIBIT M

CHAYET AND SONNENREICH, P.C.

Attorneys at Law

6 Fayette Street
Boston, Massachusetts 02116

(617) 357-0202

June 3, 1975

Dr. Theodore Cooper
Acting Assistant Secretary for Health
Department of Health, Education, and Welfare
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Cooper:

Thank you for your letter of May 23, 1975 regarding the law firm's request for information relating to the University Group Diabetes Program.

As you stated in your letter, Dr. Whedon did respond to me that he did not have in his physical possession the raw data upon which the UGDP study was based. However, I call to your attention the fact that this study was funded entirely by the National Institute of Health of the Department of Health, Education and Welfare, and unless a specific provision was written into the original contract authorizing this study, the materials collected, which would include computer tapes and other means of study, storage and analysis, are the property of the United States Government and therefore are constructively in the possession of the Government. Since such materials have been paid for with Federal funds, it is, in our judgment, entirely appropriate for the National Institutes of Health to request that such raw data be made available to us regardless of

where it is being kept and stored. It is our belief that the statement by Dr. Whedon that NIH does not have in its physical possession such data is begging the question; such data has been federally paid for and, under the Freedom of Information Act, should be available.

I would like it clearly understood that we are not concerned with breaching any confidentiality in terms of patient identity. We are making this request so that the basic materials upon which a scientific controversy has raged can be carefully reviewed and analyzed. It is our belief that such raw data does in fact "belong" to the Department of Health, Education, and Welfare and, upon your request to whoever is the custodian, it can be made available for such analysis.

With respect to our request for the UGDP study research design and protocol, we are appreciative of your transmitting our request to NIH. It is our belief that once we have in hand all materials requested, we will be able to be more completely informed about the basic foundation upon which any hypotheses have been drawn in the UGDP study.

Yours truly,

/s/ NEIL L. CHAYET
Neil L. Chayet

NLC/sjm

EXHIBIT N

CHAYET AND SONNENREICH, P.C.

Attorneys at Law

6 Fayette Street
Boston, Massachusetts 02116

(617) 357-0202

July 8, 1975

Theodore Cooper, M.D.
Assistant Secretary for Health
Department of Health, Education, and Welfare
Public Health Service
Washington, D.C. 20201

Dear Dr. Cooper:

I am in receipt of your letter of June 24, 1975 responding to my formal request to you for the raw data relating to the University Group Diabetes Program study.

I am somewhat perplexed by your answer that such material not available to the Department of Health, Education, and Welfare, in light of the recently published Federal Register regulations relating to the oral hypoglycemic drugs (40 FR 28587 et seq.). I direct your attention to 40 FR 28589, where the Commissioner of the Food and Drug Administration states that a study was contracted, through the National Institute of Arthritis, Metabolism, and Digestive Diseases, to the Biometrics Society to do an in-depth assessment of the scientific quality of the UGDP study. It is obvious that such study has to examine the raw data and, in fact, the regulations state that the Biometrics Society "... made new analyses from the original data." (40 FR 28590). If such material was available to the Biometrics Society, fairness and evenhand-

edness would dictate that the Department of Health, Education, and Welfare would also see to it that such material is made available to the Committee on the Care of the Diabetic, especially in light of the preamble of Commissioner Schmidt in the proposed rules relating to oral hypoglycemics, where he recognizes the legitimacy of concern by the Committee on the Care of the Diabetic and the nature of the scientific controversy.

It is the hope of the CCD that this controversy can be resolved through scientific analysis rather than legal recourse. It is for this reason that I again respectfully request that the raw data that was made available to the Biometrics Society and which is the basis of the UGDP controversy be made available to the Committee on the Care of the Diabetic.

I look forward to an early reply to this request.

Yours truly,

/s/ NEIL L. CHAYET
Neil L. Chayet
Counsel
Committee on the Care of the Diabetic

EXHIBIT O

CHAYET AND SONNENREICH, P.C.

Attorneys at Law

6 Fayette Street
Boston, Massachusetts 02116

(617) 357-0202

July 11, 1975

Mr. Linden F. Neff
Grants Management Officer
National Institute of Arthritis,
Metabolism and Digestive Diseases
5333 Westbard Avenue, Room 610
Bethesda, Maryland 20014

Dear Mr. Neff:

Thank you for the courtesy of meeting with me on July 7 relative to this law firm's request on behalf of the Committee on the Care of the Diabetic (CCD) for information concerning the UGDP study, research design and protocol and additional budgetary documents under the Freedom of Information Act (see letter of Neil L. Chayet, Esq. to Dr. Theodore Cooper of May 6, 1975).

In the course of my review of the documents which you provided, I requested that the following documents be photocopied and transmitted to our offices:

1. Monies awarded by NIAMDD to each institution participating in the UGDP study for each year of the study;
2. Return of Expenditures (ROEs) for each institution participating in the UGDP for each year of the study;

3. Progress Reports prepared by each institution and by the UGDP Coordinating Center for each year of the study;
4. All newsletters and minutes prepared by the Coordinating Center during the course of the study;
5. Original research design and protocols for each institution participating in the study;
6. Samples of all DHEW forms that have been used to certify institutional compliance with rules relative to protection of human subjects;
7. Assurances filed by each institution during the course of the study that informed consent from the patient had been secured, including actual informed consent forms;
8. Copies of all documentation in the file relative to the UGDP Coordinating Center;
9. Copies of all documentation in the file relative to the University of Maryland as a participating institution (Principal Investigator—Dr. Christian Klimt).

We agreed that photocopying of the above materials, with the exception of Items 8 and 9, would begin immediately and that the materials would be sent as soon as ready and hopefully within the next week. We further agreed that you would telephone me on July 14, 1975 to give me an estimate of the effort involved in reproducing Items 8 and 9.

In the course of our meeting, you informally indicated that you were not authorized to provide CCD with copies of summary statements submitted by peer groups reviewing the merits of the UGDP study as it has been conducted from 1960 to the present time. You further indicated that information relative to personnel salary would not be made

available. CCD hereby makes formal request for access to such information. In addition, CCD specifically reserves the right to request additional information under the Freedom of Information Act as it becomes aware of the existence of such information.

Once again, let me thank you for your courtesy and cooperation.

Very truly yours,

Harvey W. Freishtat

HWF/sjm

EXHIBIT P

DEPARTMENT OF HEALTH, EDUCATION, AND
WELFARE

OFFICE OF THE SECRETARY

WASHINGTON, D.C. 20201

July 30, 1975

Received July 31, 1975, Chayet and Sonnenreich, P.C.

Mr. Harvey W. Freishtat
Chayet and Sonnenreich, P.C.
6 Fayette Street
Boston, Massachusetts 02116

Dear Mr. Freishtat:

Reference is made to your letter dated July 11, 1975, addressed to Mr. Linden F. Neff, Grants Management Officer, National Institute of Arthritis, Metabolism, and Digestive Diseases. Your request has been forwarded to me because of my responsibilities under the Freedom of Information Act. The Department's policy is one of the fullest possible disclosure limited only by the obligations of confidentiality and the administrative necessities recognized by the Act. Copies of the FOI Act (5 U.S.C. 552) and the Department's implementing Public Information Regulation are enclosed and referred to below.

It is my understanding that in order for you to better define what you really wanted from the NIAMDD files, arrangements were made for you to visit the NIH on July 7, 1975, to review material relating to the UGDP Study. Subsequent to this meeting you requested copies of a more specific list of documents. It is our intention to release all of the information requested, except; (1) specific parts of each summary statement that reflect only opinions of the con-

sultants serving as members of the initial review group and (2) salaries of individuals named in the applications. In the appendix of the Department's implementing Public Information Regulation (45 CFR Sec. 5.73) it is stated that summaries of recommendations of review groups (pink sheets) are generally not available. In addition, opinions in inter-agency or intra-agency memoranda or letters made by government officers, employers, or consultants may be denied in accordance with 5 U.S.C. 552(b)(5) of the Freedom of Information Act.

In view of the above, all opinions of the consultants serving as members of the initial review group will be deleted from the summary statements before they are released. Salaries of individuals named in the research grant applications are denied in accordance with 5 U.S.C. 552(b)(4) of the Freedom of Information Act and 45 CFR 5.71 of the Public Information Regulation, since disclosure would constitute a clearly unwarranted invasion of personal privacy.

You have the right to appeal this decision within thirty (30) days. Should you wish to do so, the procedure is outlined under Subpart G of the Department's Regulation. Any such appeals should be addressed to the Assistant Secretary for Health, Department of Health, Education, and Welfare, 330 Independence Avenue, S.W., Washington, D.C. 20201.

Sincerely yours,

/s/ RUSSELL M. ROBERTS
Russell M. Roberts
Freedom of Information Officer
Office of Public Affairs

Enclosure

EXHIBIT Q

DEPARTMENT OF HEALTH, EDUCATION, AND
WELFAREPublic Health Service
Washington, DC.. 20201

August 7, 1975

Neil L. Chayet, Esq.
Chayet and Sonnenreich, P.C.
6 Fayette Street
Boston, Massachusetts 02116

Dear Mr. Chayet:

In response to your additional request regarding the raw data relating to the University Group Diabetes Program study, I have made further extensive inquiries of both the National Institutes of Health and the Food and Drug Administration.

Neither agency has ever had the raw data in its possession. The FDA labeling recommendations were based on the data that has been published by the UGDP in several articles and the review of the UGDP study by the Biometric Society.

The UGDP study itself was funded as a grant by the National Institute of Arthritis, Metabolism and Digestive Diseases. It was begun in 1961 and, as you know, included 12 university medical school clinics. The coordinating center for the study and the data was and is the University of Maryland in Baltimore. The coordinating center director is Dr. Christian R. Klimt.

When the NIH awards a grant the only data requirements imposed by that grant are, generally, the submission of interim and final reports. Final reports are most often in

the form of journal publications, as has been the case with both the UGDP study itself and the Biometric Society report. It has not been the practice of the NIH to require that grantees submit their raw data, and no raw data was ever submitted in connection with the UGDP study. No provision of either the UGDP grant or the Biometric Society contract requires the submission to the NIH of raw data.

It appears, therefore, that the raw data is the property of the individual investigators and the coordinating center. Given that this is the case, this Department has, as stated previously, no authority to order that the data be made available in any form other than those reports required by the grant and the contract, and those reports have all been published.

I am informed that the raw data is now in the form of microfilm and is stored in a Maryland bank vault. I am also informed that Dr. Klimt, who states that he has spoken with the Attorney General of the State of Maryland on this subject, feels the data is protected from disclosure under Article 76A of the Annotated Code of Maryland. While I cannot, therefore, suggest it as a fruitful approach, it would appear that further efforts on your part should be directed to Dr. Klimt. His title and address are:

Professor and Director
Division of Clinical Investigation
University of Maryland School of Medicine
Baltimore, Maryland 21201

I regret that I cannot be of more help in this matter.

Sincerely yours,

/s/ THEODORE COOPER, M.D.
Theodore Cooper, M.D.
Assistant Secretary for Health

EXHIBIT R

CHAYET AND SONNENREICH, P.C.

ATTORNEYS AT LAW

6 FAYETTE STREET

BOSTON, MASSACHUSETTS 02110

(617) 227-0101

August 7, 1975

Theodore Cooper, M.D.
 Assistant Secretary for Health
 Department of Health, Education, and Welfare
 Public Health Service
 Washington, D.C. 20201

Dear Dr. Cooper:

I am in receipt of your letter of August 7, 1975 which denies the request of the Committee on the Care of the Diabetic (CCD) for the University Group Diabetes Program (UGDP) study raw data. I must confess that I am shocked by the fact that both the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) have not studied the basic data of the UGDP study and have, instead, relied solely on journal articles in reaching the sweeping conclusions made with respect to oral hypoglycemics.

Given the nature of this five-year scientific dispute, it is astonishing that scientific personnel within the FDA and NIH would not have reviewed their basic data in light of the controversy which has raged within the scientific community concerning the validity of the UGDP study. It is our judgment that this failure of the FDA to so study this data amounts to gross scientific negligence and a real disservice to the public. It further casts even more doubt on

the conclusions reached by FDA in its regulations concerning the labeling of oral hypoglycemic drugs.

On behalf of the Committee on the Care of the Diabetic, I wish to inform you that your refusal to make available the raw data of the UGDP study on the theory that it belongs solely to Dr. Klimt is not acceptable either in law or in fact. Therefore, the CCD believes it has exhausted all administrative remedies possible and wishes to inform you that it will take the matter to court in the immediate future.

Yours truly,

/s/ NEIL L. CHAYET
 Neil L. Chayet
 Counsel
 Committee on the Care of the Diabetic

cc: Dr. Alexander Schmidt

EXHIBIT S

(The following statement was telegraphed to the Commissioner of the Food and Drug Administration on December 1, 1970)

Statement On The Treatment of Diabetes

Uncritical and premature recommendations of the Food and Drug Administration regarding the treatment of diabetes mellitus are to be deplored. This is the conclusion reached by forty diabetes specialists who met on November 30, 1970, at the Sheraton-Boston Hotel to discuss their mounting concern for more than one million diabetic patients who have become increasingly disturbed because of newspaper stories alleging adverse effects from long term use of oral anti-diabetes agents.

The current controversy arose following a scientific presentation on June 14, 1970, at the annual meeting of the American Diabetes Association in St. Louis. At that time a group of 12 university centers known as the University Group Diabetes Program (UGDP) presented the results of an 8-year study of more than 800 diabetic patients subjected to different forms of treatment. This prospective cooperative clinical study *appeared* to show that administration of a sulfonylurea drug (tolbutamide) to mild adult-onset diabetes led to a greater death rate from cardiovascular disease than was found in three other groups treated with diet alone, a fixed dosage of insulin or a variable dosage of insulin. The report received widespread news coverage. Subsequently a letter sent by the ADA to its membership on October 27, 1970, supported the validity of this study, as did a report from the American Medical Association's Council on Drugs.

In late October, an official Food and Drug Administration "Current Drug Information" bulletin was sent to all physicians in the United States. Although based upon still un-

published findings, the letter contained far-reaching implications regarding the future treatment of diabetics. Portions of the FDA statement that may significantly affect diabetic management and greatly compromise the freedom of the physician to prescribe for his patients are as follows:

(1) "Oral hypoglycemic agents should be used only in diabetics with adult-onset, stable disease which cannot be controlled by diet alone and for whom insulin is unacceptable or impractical. A recently published study shows NO evidence that, in diabetics with adult-onset, stable diseases, therapy with a fixed dose of one such agent (tolbutamide) and diet is more effective in prolonging life than diet alone. The study also suggests that such a regimen may be less effective insofar as cardiovascular mortality is concerned than diet alone or than diet and insulin combined."

(2) In the words of Dr. Charles C. Edwards, Commissioner of Food and Drugs, "The initial and essential foundation for the management of adult-onset diabetes mellitus is diet and weight control. When the symptoms of the disease are adequately controlled by these measures, no other therapy is indicated. All oral hypoglycemic agents should be employed with caution and, if prescribed, then only when serious application of diet, or diet plus insulin has been proven ineffective in the judgment of the physician."

"A physician using hypoglycemic agents should familiarize himself with the cautionary material in the package inserts for these drugs and should adjust the dosage according to the individual patient's needs."

(3) Recommendations that extend the interpretation of the results of the UGDP study to the use of all currently available oral hypoglycemic agents are as follows: "The Food and Drug Administration recommends that the use of Orinase (tolbutamide) and other sulfonylurea type agents, Dymelor (acetohexamide), Diabinese (chlorpropamide),

Tolinase (tolazomide), should be limited to those patients with symptomatic adult-onset nonketotic diabetes mellitus which cannot be adequately controlled by diet or weight loss alone and in whom the addition of insulin is impractical or unacceptable. The oral hypoglycemic agents are not recommended in the treatment of chemical or latent diabetes, or in pre-diabetes, and are contraindicated in patients with keto-acidosis."

The actions of the FDA are based exclusively upon this solitary report by the UGDP. Yet, the absence of any similar observations during vast experience with large numbers of diabetic patients, both here and abroad, for periods up to 15 years in the use of tolbutamide and other oral hypoglycemic agents prompted this re-examination of the UGDP report.

The assembled group of diabetes specialists recognized numerous limitations of the UGDP study, including the following:

(1) There was no significant difference in overall mortality among the four treatment groups. Regarding the alleged excess of cardiovascular deaths in patients treated with tolbutamide, the lack of homogeneity of baseline risk factors in the 12 treatment centers invalidates statistical evaluation of the findings.

(2) Disagreement persists concerning the evaluation of the data by UGDP statisticians, since the application of different statistical methods has yielded contradictory results. For example, one independent analysis found no significant difference between tolbutamide and placebo groups with respect to cardiovascular deaths, either when tested separately within each of the 12 treatment centers or when the summed results of all 12 centers were analyzed.

(3) Spontaneous levelling of the claimed excessive mortality in tolbutamide-treated patients during the eighth and

last year of the UGDP study suggests that the alleged increase in cardiovascular deaths is not due to the administration of the drug.

Other matters were criticized severely by the group. The application of an arbitrary, constant dosage of tolbutamide differs radically from the customary clinical usage of the drug. The fact that therapy seemed to have little or no effect on maintaining normal blood sugar levels was attributed to the use of the fixed dosage of tolbutamide, which is also the shortest-acting of the sulfonylurea compounds. Furthermore, the well-known phenomenon of secondary failure known to occur in 30 percent or more of patients so treated was apparently ignored in this report as a possible cause for the elevated blood sugar levels observed.

Findings such as these made the group feel that the established treatment of diabetes was under significant pressure on the basis of experimental results of dubious validity.

The consensus of the meeting was that, before any further action is taken by regulatory agencies, the raw data should be made available to the scientific community at large.

The disastrous consequences of this report stem from the fact that it will tend to restrict treatment of patients with latent or asymptomatic hyperglycemic who do not respond to diet alone.

We categorically oppose the uncritical and premature recommendations of the FDA based on the single and still unpublished report of the UGDP, which is scientifically unacceptable to many specialists in diabetes. This unprecedented interference with the treatment of patients in a controversial area is not only outside the province of a governmental regulatory agency, but it has also damaged the welfare of more than a million diabetic patients.

The erroneous and insensitive manner in which purported information has been disseminated for the past six months has further burdened both physicians and the diabetic population at large with unwarranted anxiety over the treatment of the disease. The FDA action has been taken despite many contrary studies both there and abroad.

The recommendation restricts and all but prohibits the use of any and all oral agents in the treatment of diabetes, despite overwhelmingly favorable clinical experiences to the contrary. Furthermore, the therapeutic implications outlined are ambiguous and impossible to fulfill in accordance with established medical practice. The recent FDA recommendations for the treatment of diabetes seriously undermine the progress made on behalf of the diabetic through years of hard work and education, in the following respects:

(1) Diabetics and their families are confused, anxious, and uncertain of their physician's ability to guide their treatment. Progress in employment and insurance status will, in many instances, be pushed back a number of years by the enforced use of insulin treatment.

(2) The physician has had no basis for making his own decisions concerning the validity of the UGDP study. Yet, he is now forced, at least indirectly, into the use of principles in diabetic treatment prescribed by the FDA. Potentially, he is exposed to an unprecedented series of malpractice suits based on any occurrence of cardiovascular problems. Though these occur with great frequency in all diabetic patients, they may now be blamed upon the taking of an oral hypoglycemic agent.

The recommendations of the FDA tend to constitute the practice of medicine by specifying the order in which therapeutic programs are to be employed in the treatment of patients. This directive, if taken literally, will also prevent or seriously hamper future clinical research in this field. Fur-

thermore, the FDA denies the value of chemical control of the disease, which emasculates any programs of diabetes detection as well as all public health measures in this area.

We request:

(1) Suitable modifications of the FDA Drug Information Letter. (2) Immediate reconsideration of currently proposed revisions of the package inserts demanded of the manufacturers of oral hypoglycemic agents, and (3) Further independent statistical and clinical analysis of the UGDP study based on raw data so far not available to the scientific community.

Signing the Position Statement are:

Robert F. Bradley, M.D.
Medical Director,
Joslin Clinic
Boston, Mass.

Peter H. Forsham, M.D.
Director, Metabolic Research Unit
University of California Medical Center
San Francisco, California

Henry Dolger, MD.
Clinical Prof. of Medicine
Mount Sinai School of Medicine
City University of N.Y.
New York, New York

Holbrooke Seltzer, M.D.
Chief of Endocrinology
Veterans Administration Hospital
Southwestern Medical School
Dallas, Texas

James B. Ashmore, M.D.
Professor of Pharmacology
Indiana University School of Medicine
Indianapolis, Indiana

Samuel B. Beaser, M.D.

Lecturer in Medicine
Tufts Medical School
Boston, Mass.

David R. Challoner, M.D.

Associate Professor
Assistant Chairman, Department of Medicine
Indiana University School of Medicine
Indianapolis, Indiana

Rafael A. Camerini-Davalos, MD.

Associate Professor in Medicine
Director, Diabetes
New York Medical College
New York, New York

Gerald Kent, M.D.

Associate Clinical Professor of Medicine
University Hospital
Case Western Reserve University
Cleveland, Ohio

Leo P. Krall, M.D.

Director of Education
Joslin Diabetes Foundation
Boston, Mass.

Arthur Krosnick, M.D.

Coordinator, Diabetes, Endocrine,
and Metabolic Disease Program
Div. of Chronic Illness Control
Dept. of Health
Trenton, New Jersey

Alexander Marble, M.D.

President
Joslin Diabetes Foundation
Boston, Mass.

Glen W. McDonald, M.D. (Ret.)

Former Chief
Diabetes and Arthritis Control Program
U.S. Public Health Service
Norman, Oklahoma

Leona Miller, M.D.

Associate Professor of Medicine
University of Southern California School of Medicine
Chief, Diabetes Service
Los Angeles, California

James M. Moss, M.D.

Clinical Professor of Medicine
Georgetown University
Washington, D.C.

Henry J. Oppenheimer, M.D.

Associate Professor of Clinical Medicine
St. Louis University School of Medicine
St. Louis, Missouri

John B. O'Sullivan, M.D.

Chief, Diabetes and Arthritis
Field Research Unit
U.S. Public Health Service
Boston, Mass.

Marjorie Peebles-Meyers, M.D.

President, Michigan Diabetes Association
Detroit, Michigan

O. Peter Schumacher, M.D.

Cleveland Office
Cleveland, Ohio

Charles Shuman, M.D.

Professor of Medicine
Temple University Health Services Center
Philadelphia, Pennsylvania

Abraham A. Silver, M.D.
Physician-in-Chief
North Charles Hospital
Baltimore, Maryland

Charles W. Sisk, M.D.
Regional Research Coordinator
Veterans Administration
Washington, D.C.

J. Stuart Soeldner, M.D.
Associate Professor of Medicine
Harvard University School of Medicine
Boston, Mass.

John W. Stephens, M.D.
Portland, Oregon

George Welsh, M.D.
President, New England Diabetes Association
University of Vermont Medical School
Burlington, Vermont

Also Signing the Position Statement are:

Seymour Alterman, M.D.
Clinical Assistant Professor of Endocrinology
University of Miami
Miami, Florida

Shepard G. Aronson, M.D.
New York, N.Y. 10022

James B. Ashmore, M.D.
Professor of Pharmacology
Indiana University School of Medicine
Indianapolis, Indiana

Edward Bader, M.D.
Chief, Diabetic Service
Jewish Memorial Hospital
Bronx, New York 10457

Donald Barnett, M.D.
Joslin Clinic
Boston, Massachusetts 02215

Samuel B. Beaser, M.D.
Lecturer in Medicine
Tufts University
Boston, Massachusetts

Lewis H. Biben, M.D.
Clinical Assistant Professor of Medicine
George Washington University Medical Center
Washington, D.C. 20006

Robert F. Bradley, M.D.
Medical Director
Joslin Clinic
Boston, Massachusetts 02215

George Brown, M.D.
Chief of Diabetes Clinics
Bronx-Lebanon Hospital Center
Bronx, New York 10453

R. A. Camerini-Davalos, M.D.
Associate Professor in Medicine
New York Medical College
Director, Diabetes Center
New York, New York 10029

John J. Canary, M.D.
Director, Division of Endocrinology and Metabolic
Disease
Georgetown University Hospital
Washington, D.C. 20007

William Castelli, M.D.
Department of Preventive Medicine
Harvard Medical School
Boston, Massachusetts 02115

David R. Challoner, M.D.
Associate Professor
Assistant Chairman, Department of Medicine
Indiana University School of Medicine
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EXHIBIT T

1.1 SPECIFIC OBJECTIVES

The aim of the study is principally to determine the relative effectiveness of four different treatment schedules in preventing the principal late complications of diabetes mellitus among diabetics able to live an asymptomatic life without insulin. The late complications of primary concern in this study are retinopathy, cardiac and peripheral vascular disease, nephropathy and possibly neuropathy. The four treatment groups are as follows:

- a. standard diet plus placebo tablets;
- b. standard diet plus a standard dose of tolbutamide;
- c. standard diet plus a standard insulin dose; and
- d. standard diet plus insulin in varying amounts dosed to maintain normoglycemia.

As yet, no positive proof has been presented that the treatment of diabetes with insulin or tolbutamide has a beneficial effect on the prevention, delay or alleviation of what are believed to be late complications of the disease. In the case of mild diabetes, where normal life is possible without the daily administration of insulin or tolbutamide, the disadvantage of such administrations from the health, convenience and economic point of view has to be weighed against possible advantages in the field of chronic complications. Only a long term prospective study with the inclusion of a negative control (diet plus placebo only) and a positive control (diet plus insulin ad. lib.) will shed some light on this question.

Since the advent of insulin in 1922 and more recently the antibiotics, mortality from diabetes and from the acute complications of the disease have been demonstrably reduced. It appears, however, that because of this prevention

of death, diabetics are increasingly able to procreate. This in turn has increased the gene frequency for the disease. As a matter of fact, there is tentative evidence that diabetes prevalence may actually be on the increase beyond what would be expected because of the aging of the U. S. population.

1.2 GENERAL PLAN

In each of the participating clinics recently diagnosed cases of mild diabetes will be subjected to a four week observation period while treated with diet alone. If they remain free of signs and symptoms of uncontrolled diabetes excluding purely chemical abnormalities, they will be randomly allocated to one of the previously described four treatment groups. A separate random allocation schedule will be maintained for each participating clinic by the Coordinating Center. Each schedule assures equal numbers in the four treatment groups at certain intervals. No clinic will be informed of the treatment allocation schedule employed until after the study is completed. The placebo and tolbutamide treatments will be double blind, that is, neither the patient or the clinic staff will know whether a tablet treated patient is receiving placebo or tolbutamide. In the case of the insulin treatment groups only the patient will be unaware of the manner in which his treatment dosage is prescribed. In one case it will be on the basis of the patient's body surface and in the other case it will be determined by the physician in such a manner as to maintain normoglycemia.

A baseline evaluation of the patient's health status will be carried out upon entry of the patient into the study. This baseline examination for complications, as it will be referred to in this protocol, will consist of four individual examinations. One deals with the eyes, another with the heart, a third with the kidneys, and a fourth deals with the peripheral vascular system. The eye examination entails

measurement of visual acuity, the distant Snellen, and two retinal photographs of each eye. The heart examination consists of resting and post-exercise ECG's, systolic and diastolic blood pressure measurements and 6' P-A teleo-chest x-ray. The kidney examination involves a urine protein determination and both blood and urine quantitative creatinine determinations. The peripheral vascular examination involves the use of soft tissue x-rays of both legs and feet as well as oscillometric measurements at three sites on both legs.

The patient will be required to keep a record of the tests for urine glucose and ketones that he will be asked to perform during the periods between clinic visits. At intervals of three months the patient will be asked to present himself at the clinic for what will be referred to as a quarterly examination. At this time the degree of control of the patient's diabetes will be determined. This determination will be based primarily upon the patient's test records and tests performed by the clinic for urine and blood glucose as well as on the clinical judgment of the physician. A temporary or permanent treatment change, and consequently failure of the originally prescribed treatment may result if ketonuria and/or signs and symptoms of uncontrolled diabetes are found.

One of the four examinations for complications will be coupled with each quarterly follow-up examination. In this manner a complete cycle of examinations will be completed in the course of any twelve month period. The order of coupling will be eye, heart, kidney and peripheral vascular. That is, the eye examination will be coupled with the first quarterly examination. The heart examination will be coupled with the second quarterly examination and so forth. These findings, in connection with the corresponding baseline examination results, can then be used to determine the onset and progression or regression of any complication.

Wherever possible the determination of critical endpoints for patients from all clinics will be entrusted to two or more specialists, who will arrive at their conclusions solely on the basis of the record of a specific examination, such as the ECG tracings, the fundus photographs or the soft tissue x-rays. Thus bias should be largely excluded and the consistency as well as the quality of the findings enhanced. The records will be forwarded from the clinics to the specialist consultants via the Coordinating Center and will only be identifiable by a code number. The consultants will be unaware of the treatment the patient is receiving. Through unannounced resubmission of already interpreted examination records to the same and to other expert consultants uniformity of interpretation will be checked at periodic intervals during the study.

The results from each clinic will be pooled provided certain conditions are met (see chapter 7) and subjected to statistical analysis at the Coordinating Center. The four treatment groups will be compared with respect to the number of deaths observed in each of the groups. In addition, the proportion among each treatment group developing one or more late complications will be compared. The proportion of clinic treatment failures among placebo, tolbutamide and standard dosage treatment groups will also be of interest. Some comparisons of interest cannot be made until the study has been completed because of their very nature, while others will be made at periodic intervals throughout the study. The analysis of the data will be facilitated with the use of IBM punch cards and IBM machines.

A detailed system to be employed in locating patients who are temporarily lost to the study, as well as a system to maintain a patient's cooperation when once in the study has been worked out (see chapter 5). These procedures must be employed to minimize the dropout rate. However, in those cases where a dropout does occur an annual evalu-

ation of the patient's status as to whether living or dead will be made. In these cases, as well as for non-dropouts, mortality constitutes a final endpoint for assessment of the relative merits of the different treatment groups.

Records for the entire cooperative study and periodic analysis of results will be centralized in the Coordinating Center. The Coordinating Center will also be responsible for maintaining uniformity in the records as well as in the laboratory techniques employed by each of the clinics. The Coordinating Center will also conduct ancillary studies aimed at either standardizing technical procedures or at developing them to such a degree that they will become a suitable diagnostic tool within the study.

1.3 ORGANIZATION AND SUPPORT

The study constitutes a collaborative effort of seven clinics and the Coordinating Center. The group chairman is Dr. Max Millner and the rapporteur is Dr. Harvey Knowles. Dr. Christian Klimt is director of the Coordinating Center and Dr. James Pratt is the liaison officer with the National Institute of Arthritis and Metabolic Diseases (NIAMD).

The study is being supported by individual research grants from the NIAMD to each of the participating clinics as well as to the Coordinating Center.

Support has been granted for the maximal permissible period of seven years. It is possible, however, that this period may have to be extended beyond this point in order to obtain conclusive results particularly with respect to some of the endpoints of interest.

The entire group will meet semi-annually to discuss current problems, proposed protocol changes, progress made, and available results. The site of the meeting will rotate among the locations of participating clinics. The post of co-chairman will be held by the host of the semi-annual meeting.

Members of the Coordinating Center will make periodic visits to each of the participating clinics. The purpose of these will be to aid in solution of problems peculiar to a particular clinic, as well as to review the record keeping system employed by the clinic. Occasionally the Coordinating Center may recommend an exchange of technical personnel if this is deemed necessary for purposes of training and standardization of technique.

1.4 HISTORY AND TIME SCHEDULE OF THE PROJECT

The development of this project can be divided into four phases. The first phase began in June, 1959, with a meeting in Atlantic City. At this time the basic objectives of the project were discussed and the principal aspects of the designs were set down. Additional meetings held in Cleveland during September, 1959, and January, 1960; in Los Angeles during January, 1960; in Brooklyn during May, 1960; in Miami during June, 1960; and in Boston during July, 1960, served to crystallize and expand upon the concepts set forth at the Atlantic City meeting.

STATISTICAL ANALYSIS OF THE DATA

7.1 INTRODUCTION

This chapter is an attempt to foresee the possible outcome of the current study as it relates to the data and conditions the analysis of the same. As such an attempt, it must be recognized that any statements concerning the analysis must, by the nature of being a forecast, be somewhat tentative. In the main we expect to be able to carry out the plans outlined herein; but it will be somewhat surprising if at least minor modifications are not necessary in many aspects. Thus, the proposed analyses set forth in this chapter are to be interpreted as provisional and subject to change as we learn by proceeding with the study.

All of the analyses to be performed must be made to coincide with the measurements to be collected. In this study, the "measurements" are the end points which have been agreed upon, and the time of occurrence of one of several end points in each patient, if they occur. Thus, the first step in considering the analyses to be performed is to have a clear statement of the conditions that will be classified as end points in any patient. (These will be provided at a later date).

7.2 THE ANALYSIS

a. Fixed Sample Size Approach Versus Sequential Analysis

In considering the statistical design of a study such as this one, the main question to be answered concerns the size of the group needed to be assigned to the various treatment groups. If this problem is to be settled a priori, certain other questions must be settled as is the situation in any case. However, the question

to be discussed here is one of approach; is it advisable to use pre-selected, fixed sample sizes (i.e., the "classical" method) or would it suit purposes better to use sequential methods. This latter method, due principally to the late Abraham Wald, has merits which recommend it. Primarily, the advantage of sequential analysis lies in the fact that, on the average, results of given precision can be obtained with fewer observations, i.e., with fewer patients. This might prove to be a worthwhile consideration when we face a long term follow-up study with its attendant risk of dropouts. It would seem advisable for the main aspects of the study to use, wherever possible, the technique of sequential analysis. Where such methods are not apropos, other techniques will be employed.

b. Simple Comparisons of Interest

For any particular end point, or for one end point after another has failed to materialize (in a specified sequence) the results of the various treatments will be compared. Thus, each of the other three treatments will be compared, for example for percentages of patients dying (within 1, 2, 3, etc., years) with the percentage dying among the negative controls, i.e., the diet plus placebo group. If there are no differences with this end point, then similar comparisons will be made with the next end point, e.g., with Grade II retinopathy. If, in addition, no differences can be discerned with this end point, then the next end point will be used as the basis of the comparisons—but in each case the comparisons are to be made for the overall groups of patients treated similarly.

It is to be noted here that no effort is to be made to segregate out individuals within treatment groups according to other relevant characteristics. This does not mean, however, that we shall not do such segregation;

it means only that at the first stage gross effects of treatment *over all* sub-groups is to be examined. This will be followed at a later stage by similar comparisons of more homogeneous sub-groups within treatment groups, e.g., groups of the same sex and age, possibly race and perhaps of similar socio-economic groups. However, the comparisons outlined previously will attempt to discern an overall treatment that is superior for all population sub-groups in inhibiting the late sequelae of diabetes mellitus.

c. Life Table Approach to Each of the End Points

It may prove more informative to examine the occurrence of each of the end points (in the specified sequence) on a life-table basis within treatment groups. Thus, the average expectation of life may be remarkably longer for one treatment than another. If this is not the case, it may be true that the average expectation of *survival without a given end point appearing* may be remarkably longer for one treatment than for another. If such information can be extracted from the data to be collected, it would be a valuable addition to the knowledge of the life history of the disease.

Again, such an analysis will be complicated by the fact that the probability of a particular end point may vary with

- 1). Time since onset of the disease
- 2). Patient's age
- 3). Patient's sex
- 4). A host of other factors,

It is then clear that an analysis of the kind outlined may be required for breakdown into more homogeneous sub-groups as indicated previously under part b above.

d. Competing Risks of End Points

It is also a distinct possibility that the occurrence of one end point may influence the appearance of another. For example, the appearance of renal pathology may so condition a patient as more frequently to precipitate peripheral vascular disease, or vice versa. Thus, it may be illuminating to investigate the appearance of the various end points, both in the presence of, and in the absence of, other end points or combinations of end points. This may give us some information on the influence of the competing risks in the development of the various end points.

7.3 ASSUMPTIONS UNDERLYING THE ANALYSIS

a. Pooling of Data From Several Different Sources

The nature of a cooperative study, such as one like this, is such that the data developed for the ultimate analysis is the composite of the data of the participating clinics. Such pooling of data from different sources has its hazards, the chief one involving the question of the comparability of the data from the different clinics. If the data were collected under the same circumstances, then it is a valid procedure to pool the data for a single analysis. Thus, in order that any one or several of the analyses previously contemplated be properly applied to the pooled data of this study, the following assumptions (at the very least) must be fulfilled:

1) The Overall Dropout Rate Must be Low

This is a simple assumption that is made to ensure that a sufficient number of patients remain in the study in order to observe a differential rate of development of complications among the several treatments. This assumption would be necessary whether or not the study were a cooperative one.

2) Treatment Failure Rates Among Treatments Do Not Differ Within a Clinic

This assumption is somewhat more subtle in its implications than the previous one. The importance of this assumption is that the whole purpose of the study is to test the differential effects of the various treatments on the *late* complications, while a treatment failure refers to a failure in the clinical management of the acute aspects of the disease. Thus, while the treatment-failures might provide valuable information concerning the efficacy of the various treatments in the management of diabetes, such treatment failures make it difficult to interpret data relating to late complications.

For example, suppose that the placebo treated (negative control) patients have a high proportion of treatment-failures as compared to the insulin standard patients. That is, after varying periods of treatment on the placebo, suppose that many placebo treated patients must be changed to insulin ad lib. In such a circumstance, how is a difference in incidence of late complications between, for example, the negative and positive control groups, to be interpreted? If diet plus insulin ad lib is truly effective over diet plus placebo in diminishing the incidence of late complications, such treatment failures will diminish the *difference in incidence* between the two groups. On the other hand, if diet alone is truly effective over diet plus insulin ad lib in diminishing the incidence of late complications, the treatment failures again diminish the *difference in incidence* between the two groups. And if there is *no difference to begin with* between the two regimens in diminishing the incidence of late complications, the results are equally (or more) equivocal; and it might be possible in this situation for the propo-

nents of the insulin ad lib treatment to maintain (erroneously) that the fact that the large proportion of placebo treated patients were changed to insulin ad lib was the determinant in the equivalence of the incidence of the late complications. That is, we might find the insulin ad lib adherents erroneously claiming the credit for equality of incidence. These examples are cited merely to illustrate the potential difficulties ensuing from differential treatment failure rates among the various treatment groups.

3) Dropout Rates Among Treatment Group Within a Clinic Do Not Differ

This requirement, while not so subtle as the preceding one, is equally important. Dropouts are a form of self-selection, and differential dropout rates among the various treatment groups introduce the possibility of bias familiar to any study involving self-selection process. The whole process of random allocation to treatments, and the other devices introduced into any study such as this one are primarily concerned with the elimination of the possibility of bias. Every effort must be made to prevent dropouts which could, at once, vitiate all the other efforts to eliminate bias.

4) Uniform Treatment Failures and Dropouts Among Treatments and/or Among Clinics

As long as treatment failures and dropouts are uniform within a clinic (assumptions 2 and 3), comparisons among treatments are valid within the clinic. However, when the data are to be pooled for combined analysis, another facet must be verified in addition. Such a facet is the treatment failure rate and dropout rate *among* clinics. If both of these rates are (each by itself) uniform across clinics

then the pooling of the data from the several clinics may be safely accomplished. But if either of these rates shows a marked variation from clinic to clinic, then *again* there may be trouble in attempting to pool the data from the several clinics.

b. Difficulties Encountered if Assumptions Not Satisfied

It is possible to anticipate the kinds of difficulties that will be encountered if the assumptions 1 through 4 listed above are not satisfied. It is advisable to list these difficulties primarily to alert the participants in the study in order that they make every effort to avoid these hazards. In addition, listing the sequelae will serve to lay down certain "ground rules" in advance, in case it becomes necessary to make use of them.

1) If assumption 1 is not fulfilled, the whole point of the study will be missed. That is, there will be too few patients remaining in the study for a sufficiently lengthy period of time for the end points to be reached. "Too few" in this context means "too few in order to allow a satisfactory resolution of the relative effectiveness of the competing treatments". More simply stated, this means that a high dropout rate may leave residual sample sizes in the various treatment groups so small as to diminish the power of the statistical tests to be used to such a point that unequivocal findings will not be possible.

2) If either assumption 2 or assumption 3 (or both) is (are) not fulfilled in any clinic(s) then the trouble is real. First of all, the data among clinics becomes non-comparable; and the clinics in which the assumption(s) is (are) not satisfied may no longer be pooled with the total group. Even more of a problem is the value of the data from such a clinic for any analysis.

While it may be argued that the data from such a clinic may be analyzed separately to advantage, this argument appears open to question. Differential dropout rates certainly, and differential treatment-failure rates possibly, are selection processes on the patients. That any selection process, and these in particular, may introduce a bias in the results is a constant specter to be avoided; where such selection cannot be avoided, the results obtained are of much diminished value for establishing results. It is true that we have some plans for analysis taking into account treatment-failures; whether these will be as sound when such failure rates differ among treatments will require further investigation. But in no manner have we been able to grapple with the question of differential dropout rates; the potential biases introduced by this self-selection process do not appear to lend themselves to any method of statistical adjustment.

3) If assumption 4 is not fulfilled, then again we have real trouble. Differential dropout rates among clinics leave us in much the same equivocal position vis-a-vis self-selection biases as does this same problem within clinics. Nothing more need be said concerning this question.

However, the question of differential treatment failures among clinics introduces a whole new set of problems. As long as we remain within a clinic, differential treatment failure rates have been the result of the same group of clinicians and are, presumably, based on the same set of diagnostic criteria, the same level of diagnostic skill, and (most important) the same set of (unconscious) biases in the investigators. But when we consider the same problem across clinics, we may be dealing with *different* sets of diagnostic criteria, *different* levels of diagnostic

skill, and (most important) *different* (unconscious) biases in the investigators.

The last mentioned item is of paramount importance. It is in the (unconscious) prejudices of the investigators for or against some treatment that may lead to the introduction of biases in the results. For example, an investigator favorable to insulin may (unconsciously) lend little weight to a patient's complaint of nocturia if the patient is being treated with insulin-standard; and this same complaint may loom large if the patient is being treated with pills—either tolbutamide or placebo. Or it is equally possible for the investigator to lean over backwards and react in exactly the opposite fashion. The important point is that, so long as it is impossible to conduct the study on a double blind basis, the investigator's (unconscious) set of biases concerning the relative merits of the treatments *may introduce biases in his deciding what are treatment failures*. Differential treatment failure rates among clinics may undoubtedly be defended on the basis of dealing with different populations: "my population is older"; "my set of patients is predominantly of a different genetic origin"; "my clinic group is of a lower socio-economic class and has less understanding of the problem"; etc. Such may all be true, but it is rather difficult to document such arguments objectively. And it is always possible that, even granting these defenses as correct, it is still true that biases have crept in which damage the data beyond repair.

EXHIBIT U

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Food and Drug Administration

Rockville, Maryland 20852

September 19, 1975

Received Sept. 24, 1975, Chayet and Sonnenreich, P.C.

In reply refer to: File No. F 75-6515

Ms. Marien E. Evans
Chayet and Sonnenreich, P.C.
Attorneys at Law
6 Fayette Street
Boston, Massachusetts 02116

Dear Ms. Evans:

This is in response to your letter of August 22, 1975, denominated as a request pursuant to the Freedom of Information Act, but actually a request for information not a document.

A Notice of Claimed Investigational Exemption for a New Drug (IND) was not filed by the University Group Diabetes Program, any of the investigators involved in the program, or the manufacturers of the drugs tolbutamide or phenformin hydrochloride in 1961. The statutory requirement that an IND be filed pursuant to regulations promulgated by the Department was not added to the Federal Food, Drug, and Cosmetic Act until passage of the Drug Amendments of 1962, P.L. 87-481, effective January 8, 1963 (28 F.R. 183).

For your information, two separate IND's were subsequently filed by the UGDP Program. One of those was filed in 1967 and the other in 1971 for administrative record-keeping purposes only.

Sincerely,

/s/ SAM D. FINE
Sam D. Fine
Associate Commissioner
for Compliance

EXHIBIT V

CHAYET AND SONNENREICH, P.C.

Attorneys at Law

6 Fayette Street
Boston, Massachusetts 02116

(617) 357-0202

September 26, 1975

Mr. Richard A. Merrill
Chief Counsel
Food and Drug Administration
5600 Fishers Lane
Room 6-57
Rockville, Maryland 20852

Dear Mr. Merrill:

I am attaching, for your information, a copy of the letter we received from Associate Commissioner Sam D. Fine in response to a request made on behalf of the Committee for the Care of the Diabetic to determine whether or not an IND was filed by the University Group Diabetes Program at the initiation of its project. As you can see from Associate Commissioner Fine's letter of September 18, 1975, an IND was not filed until 1967 and again in 1971, and these were filed, according to Associate Commissioner Fine, "for administrative recordkeeping purposes only."

On behalf of the Committee for the Care of the Diabetic, I would like to know why such a project was permitted to proceed from 1961 through 1967 without the filing of an IND, and the nature of subsequent INDs filed in 1967 and 1971. Our reading of the Federal Food, Drug and Cosmetic Act would indicate that such a study would require, as a matter of law, the filing of an IND. Further, our review of

the law and regulations thereunder did not yield any special regulations relating to the filing of INDs "for administrative recordkeeping purposes only."

Before proceeding any further in this matter, we are formally requesting your legal opinion, as principal legal officer of the Food and Drug Administration, as to the legality of this UGDP study. Since it is our contention and belief that the study was carried out in clear violation of federal law, we would be most interested in knowing what actions, if any, are anticipated by the Food and Drug Administration in this regard.

I look forward to an early reply to this inquiry.

Yours truly,

/s/ NEIL L. CHAYET
Neil L. Chayet
Counsel
Committee for the Care of the Diabetic

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, *et al.*, Plaintiffs

v.

DAVID MATHEWS, *et al.*, Defendants

MOTION FOR EXPEDITED RELIEF

Now come plaintiffs in the above entitled action and move pursuant to the provisions of 5 U.S.C. § 552 and Rule 65(a) of the Federal Rules of Civil Procedure for an Order granting plaintiffs expedited relief compelling the immediate production of the raw data of the University Group Diabetes Program and the draft report of the Biometric Committee, all as more fully set forth in the Complaint, Memorandum of Points and Authorities in support of plaintiffs' Complaint, and Order on file with this Court.

Plaintiffs further move that hearing on this Motion be consolidated with trial of the action on the merits.

Respectfully submitted

CHAYET AND SONNENREICH, P.C.

By /s/ NEIL L. CHAYET
Neil L. Chayet

/s/ HARVEY W. FREISHTAT
Harvey W. Freishtat

Attorneys for Plaintiffs

6 Fayette Street
Boston, Massachusetts
617/357-0202

IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, *et al.*, *Plaintiffs*

v.

DAVID MATHEWS, *et al.*, *Defendants*

**MOTION OF DEFENDANT, DR. CHRISTIAN R. KLIMT,
TO DISMISS AND TO QUASH SERVICE OF PROCESS**

Defendant, Dr. Christian R. Klimt, by Francis B. Burch, Attorney General of Maryland, David H. Feldman and Mary Elizabeth Kurz, Assistant Attorneys General, pursuant to Rule 12(b) of the Federal Rules of Civil Procedure, moves for an order dismissing the action filed herein and quashing the service of process as to the aforementioned Defendant. The grounds for the Motion are as follows:

1. Lack of jurisdiction over the person; and
2. Insufficiency of process; and
3. Insufficiency of service of process.

In support of the Motion, the Court is respectfully referred to the Memorandum accompanying this Motion.

Respectfully submitted,

/s/ FRANCIS B. BURCH
Francis B. Burch
Attorney General of Maryland

/s/ DAVID H. FELDMAN
David H. Feldman
Assistant Attorney General

/s/ MARY ELIZABETH KURZ
Mary Elizabeth Kurz
Assistant Attorney General
201 W. Preston St. (Lobby Level)
Baltimore, Maryland 21201
(301) 383-6016
Attorneys for Defendant,
Dr. Christian R. Klimt

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, HENRY DOLGER, HOLBROOK S. SELTZER,
as they are members of the Committee on the Care of
the Diabetic, *Plaintiffs*,

v.

DAVID MATHEWS, Secretary of the Department of Health,
Education, and Welfare; THEODORE COOPER, Assistant
Secretary of Health, Department of Health, Education
and Welfare; ALEXANDER M. SCHMIDT, Commissioner
of the Food and Drug Administration; G. DONALD
WHEDON, Director of the National Institute of Arth-
ritis, Metabolism, and Digestive Diseases; CHRISTIAN R.
KLIMT, *Defendants*.

**OPPOSITION TO MOTION TO DISMISS AND TO
QUASH SERVICE OF PROCESS**

Original Filed Nov. 24, 1975

Now come plaintiffs in the above-entitled action and op-
pose defendant Klimt's Motion to Dismiss and to Quash
Service of Process for reasons set forth in the accompany-
ing Memorandum.

Respectfully submitted,

NEIL L. CHAYET

HARVEY W. FREISHTAT

CHAYET AND SONNENREICH, P.C.
Six Fayette Street
Boston, Massachusetts 02116

Telephone no.: (617) 357-0202

EXHIBIT B

UNIVERSITY OF MARYLAND

School of Medicine

Institute of International Medicine

Baltimore, Maryland 21201

Division of Epidemiology and Biostatistics

TO: NIAMD Study Section on Epidemiology and Disease
FROM: Christian R. Klimt, M.D., Dr. P. H. and Ovid B.
Bush, Jr., M.D.

SUBJECT: Pending grant application entitled "Prevalence
of Diabetes and Vascular Complications in Japan"

This is in answer to the request made by the site visiting
committee for an elaboration of certain points pertinent to
the above grant application. These points can be grouped
as follows:

1) The history of the development and conduct of the pre-
ceding study entitled "Geographic Pathology of Diabetes
in Japan" under the principal investigatorship of Dr. Dan-
iel B. Stone at the University of Iowa.

2) Amplification of reasons for locating the proposed
study in Japan. Results with regard to feasibility of pro-
posed study obtained from pilot studies. Summary of scien-
tific results obtained and lessons learned from current Iowa
based study.

RE (1):

The original grant application, submitted three years ago
by Dr. Stone from the University of Iowa essentially con-
tained the study plan as it is now being proposed. The plan
can be divided into four phases:

Phase 1: Hospital based study of selected diabetics in Japan using clinical and laboratory procedures comparable to those developed for and by the University Group Diabetes Program in the USA.

Phase 2: Pilot field studies for diabetes prevalence intended to develop technically suitable as well as practical survey methods.

Phase 3: Diabetes prevalence field study in selected localities in Japan representing different types of socio-economic communities.

Phase 4: Follow-up study for vascular complications and diet patterns of persons aged 30 and over representing the above communities. Three groups are to be followed depending on plasma glucose levels obtained under standardized conditions.

The original grant application was partially approved for a period of three years, permitting the conduct of Phase 1 and Phase 2 studies. By July, 1966 the hospital based study has followed 130 patients and four pilot field studies have been completed. This grant will continue until the end of March 1967. The present grant is intended to provide for Phases 3 and 4, i.e., the diabetes prevalence study based on approximately 20,000 persons aged 30 and over representing seven selected communities, and Phase 4, the follow-up study of approximately 1,000 persons, 250 with one hour post glucose challenge plasma values under 160 mg percent, 250 in the gray zone with corresponding plasma glucose values between 160-209 mg percent, and about 500 persons with plasma glucose values of 210 mg percent or more, i.e., the diabetic group. These 1,000 persons will be followed annually for the appearance of vascular complications in the heart, the eye, the kidney and the peripheral vascular tree.

While important information is expected to emanate from Phases 1 through 3, the core of the study is an evaluation of the rate of the appearance and development of

vascular complications by class of plasma glucose level (i.e., the presumably non-diabetic, the gray zone, and the presumably diabetic class) and the cross correlation of vascular complication rates with environmental factors such as diet.

For organizational and technical reasons it has been agreed with Dr. Daniel B. Stone (see letter attached to grant application) to transfer the study from the University of Iowa to the University of Maryland and to change the principal investigatorship from Dr. Stone to Drs. Klimt and Bush. The emphasis in Phases 3 and 4 of the study on epidemiology and statistics and on field work in Japan makes this transfer a logical one.

RE (2):

This concerns the reasons for locating the study in Japan.

A) Among the developed countries, Japan has the lowest mortality rate for diabetes. It may also have a low diabetes prevalence. Japan has a low mortality from coronary artery disease coupled with high hypertension and stroke rates. Small scale studies and clinical impressions indicate that severe vascular complications are quite rare among diabetics in Japan. The prevalence of diabetes and the rate, as well as severity of vascular complications, must be ascertained in a population based study with criteria and techniques widely used and accepted in the U.S.

B) A wide variety of diets is found in Japan. The traditional rural areas show a high carbohydrate, low fat, low animal fat, and low cholesterol diet.

On the other hand, in urban and suburban areas a cultural transition to Western type diets with high fat intake is taking place. The caloric intake does not vary much and is comparable to caloric intake in the United States. Diet patterns can be uniquely found and correlated to diabetes prevalence and onset as well as progression rates of vascular complications in Japan.

C) The University of Iowa hospital based study gives support to the hypothesis of differences in the frequency and pattern of vascular complications in Japanese diabetics.

While on the one hand, small vessel disease, particularly in the eye, is found very frequently in a selected group of diabetics, these same diabetics show very infrequent large vessel disease in the peripheral arterial tree. These findings are in strong contrast to data obtained in the University Group Diabetes Program where newly diagnosed diabetics of the same age range show equal frequencies of small and large vessel disease, the latter being about four times as frequent as found in the Japanese patients. One might lean to the conclusion that small vessel disease is an integral part of diabetic pathology, while peripheral arteriosclerosis, though possibly enhanced by diabetes, is largely influenced by environmental factors, quite possibly the type of diet consumed.

D) The pilot prevalence surveys have been conducted as part of multipurpose surveys using various screening and diagnostic techniques. The data are small in scale and, therefore, difficult to interpret and are not suitable for pooling of results as by design different techniques have been used in each pilot study. Having in mind the above restrictions, we find prevalence figures which are *not* unusually low when compared to data from the U.S. The pilot field studies had as their prime purpose the study of methods and feasibility. We have learned not to use a step-wise program beginning with urine or random blood sample screening to be followed by a glucose tolerance test in positive "screenees".

In the last pilot survey, completed during July of 1966, a group of 500 individuals, preselected to represent a defined population, were invited to come on a given date to a clinic for a short glucose tolerance test. The test was to be given to the overnight testing individual during the morning. A 50% initial response rate was obtained without any

preceding information either to the persons tested or to the medical community. This may be considered a satisfactory initial response rate which, of course, will be improved upon in the future during the actual survey by home visits, medical and lay propaganda and flexible clinic hours. It should be noted that these survey methods are in accordance with the recommendations passed by a symposium sponsored by the U.S. PHS on population based studies on diabetes (Washington, October, 1964).

E) In addition to the above mentioned scientific reasons for wishing to locate this study in Japan, the following organizational reasons may be given:

- i) Two M.D.'s from the University of Osaka (i.e., Dr. A. Sasaki, and Dr. T. Suzuki) will have been trained for two years in epidemiology and statistical methods, including computer programming at the University of Maryland in Baltimore by the first half of 1967. These two doctors will both be available full time for participation in this study.
- ii) A complete field survey team has been assembled and trained in survey procedures.
- iii) Laboratory methods have been set up at the University of Osaka on a Technicon autoanalyzer for determinations of glucose, BUN, creatinine and cholesterol. The results have been compared with the ones of duplicate samples obtained in the U.S. and found to be satisfactory.
- iv) Mrs. Joan Bickel, research dietician of the University of Iowa has given training to Japanese dieticians on diet survey techniques.
- v) Clinicians have been trained in the use of techniques, developed for and by the University Group Diabetes Program particularly with regard to: Fundus photographs, soft tissue X-rays, resting and post-

exercise ECG's, kidney function tests, and clinical examinations including skinfold measurements and biothesiometric measurements for vibratory sensitivity. They will continue to be available for this study.

vi) An administrative organization has been developed by Dr. Bush in Osaka which is capable of assuring liaison among the participating groups in Japan and with the University of Maryland in Baltimore and handling fiscal matters in accordance with University and National Institute of Health requirements.

vii) Certain equipment and facilities are already available (i.e., one autoanalyzer, a Zeiss camera for fundus photography, a spectrophotometer, a minus 20 degree Centigrade deep freeze, office equipment and an electric calculator.

viii) Strong relations have been forged among the participating universities, i.e., Maryland, Iowa and Osaka, through the current study, though the training program of Japanese M.D.'s in Baltimore and through prolonged visits of Dr. Seki and Dr. Wada to the United States.

ix) The cost of the proposed study could not be matched for a comparable effort in the U.S. This is mainly due to the lower Japanese salary scales.

x) The availability of technical expertise including expert readership for clinical records through the University Group Diabetes Program (UGDP). These facilities will also be available for the Japanese records and will assure comparability of findings between the two studies. Dr. C. R. Klimt and his staff in Baltimore function as the Coordinating Center for the UGDP thus assuring liaison with the proposed study in Japan. In addition, Dr. Max Miller of Cleveland, who is chairman of the UGDP, will be available as clinical diabetes consultant.

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE		PUBLIC HEALTH SERVICE		NATIONAL INSTITUTES OF HEALTH		DIVISION OF RESEARCH GRANTS	
EXPENDITURES REPORT				RESEARCH GRANTS			
READ INSTRUCTIONS ON PAGE 4 BEFORE COMPLETING THIS FORM							
TYPE OF REPORT		PERIOD		FISCAL YEAR		PHS GRANT NO.	
<input type="checkbox"/> PRELIMINARY <input checked="" type="checkbox"/> FINAL		September 1, 1960		August 31, 1961		AP-1557 (3)	
1. AMOUNT OF GRANT FUNDS RECEIVED FROM PUBLIC HEALTH SERVICE				27,100		00	
2. AUTHORIZED TRANSFERS							
3. FUNDS AVAILABLE FOR EXPENDITURE				27,100		00	
4. INTEREST EARNED (Vary) TO BE RETURNED TO PHS, D. H. E. W.							
EXPENDITURES							
5. TOTAL DIRECT COSTS COVERED BY THIS REPORT (Line 2, 3, and 4)				22,553		22	
6. INDIRECT COSTS (Line 5 of line 5)				3,111		48	
7. TOTAL EXPENDITURES PREVIOUSLY REPORTED FOR THIS GRANT PERIOD							
8. TOTAL EXPENDITURES TO DATE (Total lines 5, 6, and 7)				25,664		70	
9. CASH BALANCE (Line 8 minus line 8)				1,052		30	
10. DEDUCT OBLIGATIONS OUTSTANDING FOR PERMANENT EQUIPMENT (end of line 9)							
DATE OBLIGATED		ITEM					
		NO LETTER NECESSARY					
11. TOTAL OBLIGATIONS OUTSTANDING				0		00	
12. FREE OR UNOBLIGATED BALANCE (Line 9 minus line 11)				1,052		30	
I hereby certify that the foregoing report is true in all respects and that the expenditures and obligations have been made within the provisions of the grant and for the purposes set forth in the application recommended by the National Advisory Council.							
INSTITUTION				MAILING ADDRESS			
University of Minnesota				Minneapolis 11, Minnesota			
PLEASE TYPE NAME OF PERSON SIGNING REPORT				TITLE OF PERSON SIGNING REPORT			
R. H. Elliott				Research Contract Coordinator			
JAN 18 1962							
(DATE)				(SIGNATURE)			
I hereby certify that the above expenditures and obligations listed on this report were made with my approval.				*If the Financial Records on this Grant are not kept at this address, indicate below where Records will be available for audit.			
INVESTIGATOR(S)				BEFORE PREPARING REPORT SEE INSTRUCTIONS ON PAGE 4			
JCE/CS							

R. EXPENDITURES FOR TRAVEL (ITEMIZED)					12,359 55
DATE OF TRAVEL	NAME OF TRAVELER AND DESTINATION	TRANSPORTATION CHARGES	OTHER TRAVEL ALLOWANCES	TOTAL	
12/1/60	Dr. Christian Klint, Rochester, Minn.	12 00		12 00	
12/10/59-12/14/60	Dr. Christian Klint, San Francisco, Calif.	256 85	124 53	381 38	
12/16-12/20/60	Dr. Christian Klint, Cleveland, Ohio	85 00	25 24	110 24	
12/24-12/27/60	Dr. Christian Klint, Washington, D.C., Baltimore & New York, Washington, D.C., Baltimore & New York	114 00	231 52	345 52	
12/14-12/17/60	Dr. Curtis McIntosh, Cincinnati, Williamson, Charleston, New York, Washington D.C., Baltimore & New York	114 00	231 88	345 88	
12/12-12/13/61	Dr. Christian Klint, Cleveland	85 00	32 83	117 83	
12/12-12/13/61	Dr. Curtis McIntosh, Cleveland	85 00	13 16	98 16	
12/12-12/13/61	Dr. Curtis McIntosh, Baltimore	125 00	53 53	178 53	
12/12-12/13/61	Dr. Curtis McIntosh, Baltimore	125 00	51 51	176 51	
12/12-12/13/61	Dr. Christian Klint, Baltimore				
12/12-12/13/61	Dr. Christian Klint, Baltimore				
TOTAL		1,440 00	1,352 70	2,792 70	

A-1. EXPENDITURES FOR PERSONNEL SALARIES AND WAGES (ITEMIZED)

NAME	POSITION	MONTHS EMPLOYED	AMOUNT PAID
1. Curtis L. Belmont	Research Fellow	12	755 00
2. Dorcas H. Bridges	Secretary	12	270 00
3. Virginia P. Bulcher	Statistical Clerk	16	300 00
4. Charlotte F. Shaw	Junior Clerk	P.T.	175 00
5. Beverly J. Anderson	Buy March Expenses	P.T.	13 00
6.			
7. Social Security Contributions			37 00
8. SMI Contributions			152 00
9. Martin's Corporation Insurance			53 00
10.			
11.			
12.			
13.			
14.			
15.			
TOTAL			1805 00

B. EXPENDITURES FOR TRAVEL (ITEMIZED)

DATE OF TRAVEL	NAME OF TRAVELER AND DESTINATION	TRANSPORTATION CHARGES	OTHER TRAVEL ALLOWANCES	TOTAL
11/15-11/17/61	Charlotte Belmont-Detroit, Mich.	77 00	112 35	189 35
11/23-12/1/61	Arthur Belmont-Corona, N.Y.		31 05	31 05
11/26-12/1/61	Charlotte Belmont-Corona, N.Y.		120 10	120 10
1/11-2/17/62	Arthur Belmont-Corona, N.Y.	110 65	11 30	122 95
2/10-2/17/62	Charlotte Belmont-Corona, N.Y.			
3/1-3/17/62	Charlotte Belmont-Corona, N.Y.	210 50	135 10	345 60
4/1-4/1/62	Charlotte Belmont-Corona, N.Y.	217 75		217 75
5/1-5/1/62	Charlotte Belmont-Corona, N.Y.	217 75		217 75
TOTAL				1003 55

U. S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
DIVISION OF INTRAMURAL RESEARCHEXPERIMENTAL
BUDGET FUND NO. 10-10

SEATTLE PLANK

EXPENDITURES REPORT
RESEARCH GRANTS

READ INSTRUCTIONS ON PAGE 4 BEFORE COMPLETING THIS FORM

TYPE OF REPORT

☐ PRELIMINARY☒ FINAL

FUND NO.

10-10-10-10

FUND NO.

10-10-10-10

FUND NO.

10-10-10-10

1. AMOUNT OF GRANT FUNDS RECEIVED FROM PUBLIC HEALTH SERVICE

93,312 00

2. AUTHORIZED TRANSFERS

1,322 23

3. FUNDS AVAILABLE FOR EXPENDITURE

92,000 00

4. INTEREST EARNED (If any) TO BE RETURNED TO PHS, D. H. E. W.

EXPENDITURES

5. TOTAL DIRECT COSTS COVERED BY THIS REPORT (Include A through D)

83,225 02

6. INDIRECT COSTS

20

82,192.02

16,438 21

7. TOTAL EXPENDITURES PREVIOUSLY REPORTED FOR THIS GRANT PERIOD

8. TOTAL EXPENDITURES TO DATE (Include lines 5, 6, and 7)

99,663 23

9. CASH BALANCE (See line 3 minus line 8)

-63 23

10. DEDUCT OBLIGATIONS OUTSTANDING FOR PERMANENT EQUIPMENT (See line 9 of this report)

DATE OBLIGATED

17-1-62

11. TOTAL OBLIGATIONS OUTSTANDING

12. FREE OR UNOBLIGATED BALANCE (See line 9 minus line 11)

-63 23

I hereby certify that the foregoing report is true in all respects and that the expenditures and obligations have been made within the provisions of the grant and, for the purposes set forth in the application recommended by the National Advisory Council.

University of Maryland

2201 W. 20th St., Baltimore, Md. (21201)

NAME OF PERSON SIGNING REPORT

TITLE OF PERSON SIGNING REPORT

I hereby certify that the above expenditures and obligations listed on this report were made with my approval.

*If the Financial Records on this Grant are not kept at this address, indicate below where Records will be available for audit.

Dr. P.H.

B. Expenditures for Travel
 PHS AM 06876-03 FID KI-VS41

Date	Name of Traveler and Destination	Transp. Charge	Other Travel Allow.	Total
10/30-10/31/64	Klint, Christian R. - Washington, D.C.	\$ 9.50	\$ 19.83	\$ 29.33
12/3-12/4/64	Meinert, Curtis L. - Bethesda, Md.	12.70	20.23	32.93
12/3-12/4/64	Klint, Christian R. - New York	45.90	102.85	148.75
12/3-12/4/64	Meinert, Curtis L. - New York	12.70	101.62	114.32
12/23-25/64	Bo, Irvin P. - New York	41.70	105.00	146.70
12/27/64	Bo, Irvin P. - New York	64.70	45.14	109.84
12/27/64	Bo, Irvin P. - New York	11.00	2.15	13.15
12/27-28/64	Suzuki, Tetsuhiro - Chicago, Ill.	79.50	32.17	111.67
12/27-28/64	Meinert, Curtis L. - Washington, D.C.	93.20	50.14	143.34
12/23-25/64	Klint, Christian R. - Chicago, Ill.	65.45	46.74	112.19
12/23-25/64	Meinert, Curtis L. - Chicago, Ill.	79.00	33.92	112.92
12/3-11/64	Thomas, David B. - New York	8.70	107.55	116.25
12/1-4/64	Meinert, Curtis L. - Minneapolis	9.00	46.75	55.75
12/30-30/64	Meinert, Curtis L. - New York	21.25	48.70	69.95
12/30-31/64	Klint, Christian R. - New York	35.05	74.30	109.35
12/27-28/64	Klint, Christian R. - Washington, D.C.	9.00	14.25	23.25
12/24/64	Klint, Christian R. - Bethesda, Md.	9.00	1.00	10.00
12/19/64	Klint, Christian R. - Silver Springs, Md.	11.00	-0-	11.00
12/5/64	Klint, Christian R. - Minneapolis, Minn.	85.50	32.75	118.25
12-5/64	Tack, O. Charles - Chicago, Ill.	86.00	73.43	159.43
12-27/64	Belcher, Virginia P. - Baltimore, Md.	123.09	83.83	212.67
12/6/64	Koyon, Alfred - College Park, Md.	6.00	-0-	6.00
12/6/64	Klint, Christian R. - Bethesda, Md.	11.00	-0-	11.00
12/1-2/64	Klint, Christian R. - Washington, D.C.	9.50	9.20	18.70
12/1-2/64	Klint, Christian R. - San Juan, P.R.	148.50	132.75	281.25
12/1-2/64	Meinert, Curtis L. - San Juan, P.R.	140.70	122.90	263.60
12/1-2/64	Bo, Irvin P. - San Juan, P.R.	146.80	139.70	286.50
12/1-2/64	Bo, Irvin P. - San Juan, P.R.	253.70	50.00	303.70
12/1-2/64	Bo, Irvin P. - San Juan, P.R.	52.20	6.75	58.95
12-15/64	Klint, Christian R. - New York	55.65	36.54	92.19
12-15/64	Meinert, Curtis L. - Minneapolis	135.85	58.00	193.85
12/6/64	Local Travel	1.75	-0-	1.75
12-24/64	Wilson, P. - Washington, D.C.	9.40	-0-	9.40
12-24/64	Klontz, M. - Minneapolis	-0-	32.65	32.65
Total Travel		\$ 1,207.69	\$ 1,635.25	\$ 2,842.94

PUBLIC HEALTH SERVICE
 ANNUAL REPORT OF EXPENDITURES - RESEARCH PERIOD GRANTS

DATE RECEIVED
 FEB 1 - 1967
 DATE RECEIVED BY DGS
 FEB 22 1967

NAME AND ADDRESS OF GRANTEE INSTITUTION		GRANT NUMBER	
University of Maryland Finance and Business 660 West Redwood Street Baltimore, Maryland 21201		PHS AM 06876-04 (KI-VS41)	
PROJECT PERIOD		FROM: 9/1/64 TO: 8/31/67	
DATE RECEIVED BY DGS		THRU: 8/31/67	
Funds AUTHORIZED FOR EXPENDITURE FOR THIS BUDGET PERIOD			
PHS FUNDS AWARDED FOR THIS BUDGET PERIOD		\$ 97,805.00	
BALANCE CARRIED FORWARD FROM PREVIOUS BUDGET PERIOD(S)		\$ 23,500.00	
TOTAL AUTHORIZED FOR EXPENDITURE FOR THIS BUDGET PERIOD		\$ 97,805.00	
EXPENDITURES FOR THIS BUDGET PERIOD		Enter TOTALS from attached schedules	
PERSONNEL		\$ 53,098.01	
CONSULTANT SERVICES		8,200.00	
EQUIPMENT		550.89	
SUPPLIES		12,771.51	
TRAVEL		2,247.55	
HOSPITALIZATION		-0-	
ALTERATIONS & RENOVATIONS		-0-	
PUBLICATION COSTS		748.62	
OTHER		3,078.59	
TOTAL DIRECT EXPENDITURES		\$ 81,504.17	
INDIRECT COSTS CLAIMED (Calculated at 20% of D.C. base)		\$ 16,300.83	
TOTAL EXPENDITURES		\$ 97,805.00	
INCE END OF THIS BUDGET PERIOD (from 10 months)		\$ -0-	
REST EARNED ON PHS FUNDS (Not available for expenditure)		\$	
I hereby certify that this report is true and correct, and that all expenditures reported herein have been made in accordance with the appropriate PHS grant policies and procedures set forth in the application and award document.			
NAME AND TITLE OF PRINCIPAL INVESTIGATOR		DATE	
Christian Klint		1/26/67	
NAME AND TITLE OF GRANTEE INSTITUTION		DATE	
K. Kohlstedt, Asst. Budget Officer		1/25/67	

⊙ E. Expenditures For Travel ⊙

Date of Travel	Name of Traveler and Destination	Amount
9/9-9/10/65	David P. Wilson; Phila. Pa.	\$ 61.80
9/9-9/10/65	Curtis L. Meinert; Phila. Pa.	12.00
9/25/65	Christian R. Klint; Bethesda, Md.	10.00
9/23-9/30/65	Jacob E. Bearman; St. Louis, Mo.	121.71
9/23-9/30/65	Christian R. Klint; St. Louis, Mo.	154.24
9/23-9/30/65	Curtis L. Meinert; St. Louis, Mo.	139.06
9/23-9/30/65	Irwin P. Ho; St. Louis, Mo.	143.36
9/23-9/30/65	Phillip D. Wilson; St. Louis, Mo.	144.76
9/23-9/30/65	Beatriz R. Boschetti; St. Louis, Mo.	127.39
10/5-10/8/65	Charles O. Tack; N. Y., N. Y.	133.75
11/25/65	Wallace J. McKeel; Boston, Mass. to Balto., Md.	66.00
11/27-11/28/65	Alan S. Freedman; Cincinnati to Balto., Md. to Cinn., Ohio	98.90
1/4-1/6/66	Curtis L. Meinert; Cleveland, Ohio to Balto., Md.	40.70
1/5-1/6/66	Christian R. Klint; San Juan, P. R.	180.15
✓ 1/9-1/22/66	✓ Christian R. Klint; San Juan, P. R.	86.21
2/3/66	? Robert Osler; Boston, Mass. to Balto., Md. to Boston	61.60
2/19-2/20/66	Christian R. Klint; Minn., Minnesota	42.00
3/23/66-3/26/66	Curtis L. Meinert; Houston, Texas	230.60
4/27/66-4/28/66	Henry Blackburn; Minn. to Cleveland to Minn., Minnesota	103.58
4/27/66-4/29/66	Curtis L. Meinert; Cleveland, Ohio	65.45
4/24/66	Curtis L. Meinert; Chicago, Ill.	90.10
4/22-4/24/66	Christian Klint; Chicago, Ill.	147.60
		2216.55
12/65-3/31/66	Local Travel - \$4.40; 12.80; 1.00; 12.80	31.00
	TOTAL TRAVEL	\$ 2247.55

TOTAL -----

EXHIBIT D

UNIVERSITY OF MARYLAND

SCHOOL OF MEDICINE

INSTITUTE OF INTERNATIONAL MEDICINE

BALTIMORE, MARYLAND 21201

DIVISION OF EPIDEMIOLOGY AND BIostatISTICS

December 14, 1967

January 2, 1968

Department of Health, Education and Welfare
Food and Drug Administration
Bureau of Medicine

Dear Doctor Finkel:

Enclosed please find my application for investigational exemption (Form 1571) for phenformin and tolbutamide used in a study known as the University Group Diabetes Program. Also enclosed please find the following:

- 1) Letters from the Upjohn Company and USV Pharmaceutical Company permitting cross reference to their material on file with you. In the case of DBI-TD this reference is to NDA #12-752, and in the case of tolbutamide it is File No. NDA 10-670.
- 2) Three copies of the protocol of the University Group Diabetes Program.
- 3) Three copies each of Form 1573 from the twelve principal clinical investigators.
- 4) One copy of our major progress report, prepared in 1966.
- 5) One copy of our most recent progress report, October 1967.

- 6) A set of labels known as sealed tear off labels as used in the University Group Diabetes Program.
- 7) A copy of our form documenting written patient consent.

As you are aware the University Group Diabetes Program has been in operation since September 1960 and has just now been renewed by NIH National Institute of Arthritis and Metabolic Diseases for a period up to seven years. Since January 1966 no new patients have been added to the study and the number of active patients, which at its peak was 1,023, has dropped to 852 active patients by the end of November 1967.

The study will again be reviewed in 1970 by NIH and an independent review committee to decide how long this study should continue. The major report will be prepared by counsel (?) for this review. In the interim, relatively brief reports are being submitted annually at the time of grant renewal in May of each year. (COPY NOT CLEAR COPY NOT CLEAR — COPY NOT CLEAR — COPY NOT CLEAR). I can be reached directly by telephone at the following number, A.C. 301-727-7184.

Yours sincerely,

/s/ CHRISTIAN R. KLIMT, M.D., Dr. P.H.
Christian R. Klimt, M.D., Dr. P.H.
Professor and Director

CRK:bbb

enc

cc: All Principal Investigators, UGDP
Dr. Rosemarie Petrucelli, NIAMD
Dr. Keith Borden, Upjohn Co.
Dr. Hans Keitel, USVP Co.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIVIL ACTION No. 75-1608

PETER H. FORSHAM, et al., *Plaintiffs*

v.

DAVID MATHEWS, et al., *Defendants*

**AFFIDAVIT OF CHRISTIAN R. KLIMT IN SUPPORT OF
MOTION TO DISMISS AND TO QUASH SERVICE OF PROCESS**

CITY OF BALTIMORE

STATE OF MARYLAND, ss

Christian R. Klimt, M.D., Dr. P. H., being first duly sworn deposes and says:

1. I am a Professor in the Department of Social and Preventive Medicine at the University of Maryland School of Medicine, and am Director of that Department's Division of Clinical Investigation. As principal investigator under grants to the University of Maryland from the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), one of the institutes of the National Institutes of Health (NIH), headquartered in Bethesda, Maryland, I am Director of the Coordinating Center of the University Group Diabetes Program (UGDP).

2. Prior to becoming principal investigator under the NIAMDD grants to the University of Maryland, I was principal investigator under similar grants to the University of Minnesota. I have been Director of the Coordinating Center for UGDP since its inception in 1960.

3. The Coordinating Center is presently located at 600 Wyndhurst Avenue, Baltimore, Maryland. At no time has the Coordinating Center been located in Washington, D.C.

4. As Director of the Coordinating Center and principal investigator under the NIAMDD grants, I have filed numerous applications and reports with NIH, which as previously noted is headquartered in Bethesda, Maryland, and with the Food and Drug Administration (FDA), Bureau of Drugs, now headquartered in Rockville, Maryland, and previously in Arlington, Virginia. I have also conducted correspondence with these same agencies concerning UGDP matters. To the best of my knowledge, information, and belief, I have never corresponded with anyone on UGDP matters at the headquarters of the United States Department of Health, Education, and Welfare in Washington, D.C. Exhibit D to Plaintiffs' Memorandum in Opposition to Defendant's Motion to Dismiss and to Quash Service of Process, being a letter to Dr. Marion J. Finkel dated December 14, 1967 and January 2, 1968, was misaddressed, since Dr. Finkel was Director of the Division of Metabolism and Endocrine Drugs of the Bureau of Medicine (now the Bureau of Drugs), and her office address was Crystal Palace, Arlington, Virginia.

5. Plaintiffs' Exhibit C to their Memorandum in Opposition to Defendant's Motion to Dismiss and to Quash Service of Process refers to certain UGDP travel expenditures and lists travel to Washington, D.C. on certain dates. I have checked my personal calendars which indicate that on dates highlighted by Plaintiffs which list Washington, D.C. as my destination, I was actually only in Washington, D.C. proper on UGDP matters twice, and for the following reasons:

11/12/64—Appointment with a cardiac specialist at George Washington University

01/19/66—American Diabetes Association Meeting, Post-Graduate Course in Washington, D.C. at the Mayflower Hotel, to give a lecture entitled, "Epidemiology of Diabetes," and to chair the ADA Statistical Committee Meeting.

The remaining dates which list Washington, D.C. as the destinations actually refer either to Bethesda, Maryland, where NIH is headquartered, or to stops in Washington, D.C. while in transit to other locations, or to National Airport, in Virginia. I have used the designation "Washington, D.C." interchangeably with Bethesda, Maryland, and National Airport, in Virginia, when I have itemized expense statements as I have considered each to be in the Washington, D.C. metropolitan area for mileage allowance purposes.

/s/ CHRISTIAN R. KLIMT, M.D., Dr. P.H.
Christian R. Klimt, M.D., Dr. P.H.

Subscribed and sworn to before me this 4th day of December, 1975.

/s/ VIRGINIA ? ? ? ?
Notary Public

My Commissions Expires: July 1, 1978.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, *et al.*, *Plaintiffs*,

v.

DAVID MATHEWS, *et al.*, *Defendants*.

**MOTION TO DISMISS OR IN THE ALTERNATIVE FOR
SUMMARY JUDGMENT ON BEHALF OF THE
FEDERAL DEFENDANTS**

Original Filed Nov. 21, 1975

The federal defendants, the Secretary and Assistant Secretary of the Department of Health, Education and Welfare, the Commissioner of the Food and Drug Administration, and the Director of the National Institute of Arthritis, Metabolism, and Digestive Disease, through their attorney, the United States Attorney for the District of Columbia, respectfully move the Court to dismiss this action for failure of the complaint to state a claim upon which relief can be granted. Rule 12(b)(6), Federal Rules of Civil Procedure.

Alternatively, defendants respectfully move the Court to grant summary judgment in their favor on the ground that no genuine issue exists as to any material fact and they are entitled to judgment as a matter of law. Rule 56, Federal Rules of Civil Procedure.

In support of the motion, defendants submit herewith a statement of material facts, a memorandum of points and authorities, and the following exhibits:

Fed. Defs. Exhibit 1—Affidavit of Theodore Cooper, M.D., Assistant Secretary for Health, Department of

Health, Education and Welfare, with attached certified documents.

Fed. Defs. Exhibit 2—Public Information Regulation, Department of Health, Education and Welfare, August 1974.

Fed. Defs. Exhibit 3—Affidavit of G. Donald Whedon, M.D., Director of the National Institute of Arthritis, Metabolism and Digestive Diseases.

Defendants also submit herewith a proposed Order.

EARL J. SILBERT
United States Attorney

ROBERT N. FORD
Assistant United States Attorney

JULIUS A. JOHNSON
Assistant United States Attorney

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, *et al.*, Plaintiff,

v.

DAVID MATHEWS, *et al.*, Defendant.

AFFIDAVIT

City of Washington)
District of Columbia) ss:

Theodore Cooper, M.D., being first duly sworn, deposes and says:

1. I am the Assistant Secretary for Health, United States Department of Health, Education and Welfare. In that capacity, I coordinate the health and health-related functions of the Department and I direct the activities of the Public Health Service, which includes the Food and Drug Administration and the National Institutes of Health.

2. I am a defendant in the above-entitled matter and have read, and am familiar with, the plaintiffs' complaint.

3. As the Assistant Secretary for Health, I have authority to act on requests for review from a person who has requested records of the Public Health Service under the Freedom of Information Act and whose request has been denied in whole or in part. This authority is stated in the Department of Health, Education and Welfare Public Information Regulation, 45 CFR 5.4 and 5.82. My action on a request for review of such records constitutes final agency action.

4. I have been advised, and so state on information and belief, that Mr. Neil Chayet, on behalf of the plaintiffs, made a request under the Freedom of Information Act by letter, dated November 4, 1974, addressed to Mr. Peter Barton Hutt, then the Assistant General Counsel Food and Drug Division, for a copy of a draft report of the Biometric Society on its study of the conclusions of the University Group Diabetics Program and for the raw data upon which the report was based. (A copy of that letter is attached hereto as appendix A).

5. I am advised, and so state on information and belief, that the Department's Freedom of Information Officer denied access to the draft report on the basis that it was a draft and that the final report would be released. (A copy of the letter of the Freedom of Information Officer is attached hereto as appendix B).

6. I am advised, and so state on information and belief, that Mr. Chayet, on behalf of the plaintiffs, appealed to my predecessor, Dr. Charles C. Edwards, the denial of access to the draft report and the apparent denial of the raw data upon which the report was based. (A copy of Mr. Chayet's letter dated January 2, 1975, is attached hereto as appendix C). In response thereto, Mr. Chayet was provided with a copy of the draft report which had been provided to the Director National Institutes of Arthritis, Metabolism and Digestive Diseases (NIAMDD) National Institutes of Health, and which was published in the February 10, 1975 issue of the Journal of the American Medical Association. Mr. Chayet was also advised that no one in the Department had any of the raw data upon which the report was based. (A copy of the letter of the Director, NIAMDD, to Mr. Chayet dated January 27, 1975, is attached hereto as appendix D).

7. By letter dated May 6, 1975, (a copy of which is attached hereto as appendix E) Mr. Chayet appealed to me as Acting Assistant Secretary for Health stating that he had

not in fact been provided with a draft copy of the Biometrics Society report as he requested. He also "renewed" appeal for the raw data upon which report was based.

8. I replied by letter dated May 23, 1975, (a copy of which is attached hereto as appendix F) advising Mr. Chayet that the copy of the report furnished to him was the draft report and the only one provided to the Public Health Service. I also advised Mr. Chayet that no officer or employee had ever had any of the raw data collected by the University Group Diabetes Program and that, since that data did not constitute records of the Department of Health, Education and Welfare, I could not provide access to or copies of it to him.

9. By return letter dated June 3, 1975, (a copy of which is attached hereto as appendix G) Mr. Chayet asserted that since the University Group Diabetes Project was funded with Federal funds through a grant from the National Institutes of Health, the Department of Health, Education and Welfare should request it from the grantee in order to provide it to a requestor under the Freedom of Information Act.

10. I replied to Mr. Chayet by letter dated June 24, 1975 (a copy of which is attached hereto as appendix H) that the raw data he requested was not part of a record of this Department and could not, in my opinion, be considered even in the constructive possession of the Department).

11. By letter dated July 8, 1975 (a copy of which is attached hereto as appendix I) Mr. Chayet took exception to my statements in my letter of June 24, 1975.

12. By letter of August 7, 1975 (a copy of which is attached hereto as appendix J) I further advised Mr. Chayet that no official of the National Institutes of Health or Food and Drug Administration had ever had the raw data relating to the University Group Diabetes Program study. I further advised that it is not the practice for the National

Institutes of Health to require grantees to submit their raw data for review and that no specific provision of either the University Group grant or the Biometrics Society contract required submission of raw data to the Department of Health, Education and Welfare. I concluded that the raw data is the property of the individual investigators and the coordinating center and that the Department has no authority to order that the data be made available to Mr. Chayet or his clients.

13. Officials of the National Institutes of Health and I have cooperated with Mr. Chayet to the fullest extent possible. Mr. Chayet's law firm on behalf of his clients, has been permitted access to the entire file of the National Institute of Arthritis, Metabolism and Digestive Diseases, concerning the University Group study and, with the exception of the raw data which is the subject of this case, has been provided copies of all records requested except for data pertaining to salaries of individuals named in grant applications and portions of documents containing opinions of consultants serving as members of the initial review group who reviewed the grant applications prior to funding of the grants. Mr. Chayet has not appealed the withholding of the latter information.

14. As I have advised Mr. Chayet, the raw data he seeks on behalf of the plaintiffs is not contained in records of the Department of Health, Education and Welfare and to my knowledge has never been in the possession of any officer or employee of the Department.

15. The University Group Diabetes Study was begun in 1961 and has studied over 800 patients over a period of ten years in 12 university medical school clinics. This study is the largest controlled clinical trial of oral oglycemic agents to date and has been supported by grants from the National Institute of Arthritis, Metabolism and Digestive Diseases. Following publication of the results of the study in 1970, the preliminary results of other studies appeared

to differ. In order to assess the scientific quality of the University Group study, in particular the biometric aspects of the design, conduct and analysis of the trial as well as other trials of oral hypoglycemic agents the Director of the National Institutes of Health invited the President of the Biometrics Society to appoint a committee to consider the biometric aspects of controlled trials of oral hypoglycemic agents. The Biometric Society is a non-Governmental organization of scientists. The work of the committee selected to conduct the study was supported by a contract with the National Institute of Arthritis, Metabolism and Digestive Diseases. The Committee's report on that study is the report referred to in paragraphs 4, 5 and 6, above.

/s/ THEODORE COOPER
Theodore Cooper, M.D.
Assistant Secretary for Health

Subscribed and sworn to before me, a notary public, in and for the District of Columbia this 10th day of Oct., 1975.

/s/ Signature Illegible
Notary Public

My Commission Expires July 31, 1976.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, et al., *Plaintiff*

v.

DAVID MATHEWS, et al., *Defendants*

AFFIDAVIT

County of Montgomery)
State of Maryland)

G. Donald Whedon, M.D., being first duly sworn, deposes and says:

1. I am Director of the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD), one of the Institutes of the National Institutes of Health, (NIH), Department of Health, Education and Welfare, Bethesda, Maryland. My curriculum vitae is attached as Exhibit 1.

2. This Institute (NIAMDD), with the advice of a number of peer review committees of distinguished and highly knowledgeable scientists, is responsible for reviewing and administering research grants and contracts in the areas of arthritis and metabolic diseases in numerous university centers, research institutions and teaching hospitals throughout the United States. Support of research in the field of diabetes is a particular responsibility of NIAMDD.

3. In my position, I have, together with my colleagues, had ample opportunity to review the inception, planning, conduct and conclusions to date of a study known as the University Group Diabetes Program (UGDP). The UGDP was a long-term prospective, controlled study, undertaken in 1961 at 12 cooperating clinics to determine the incidence and development of degenerative complications of diabetes mellitus. The study was conducted in patients with newly

diagnosed, maturity-onset diabetes. Initially, the UGDP study involved four treatment regimens: (1) diet alone; (2) diet plus insulin in standard dose; (3) diet plus insulin in variable dose; and, (4) diet plus tolbutamide. In 1963 a fifth regimen was added: diet plus phenformin. Approximately 1,027 patients participated in the study, (200 per treatment group). The patients were monitored for from five to eight years.

4. The inspiration for the UGDP study came from private non-government physicians and scientists in mid-1959. Between 1959 and 1961, before the study actually began with the entry of the first patients, the design, methods, and objectives of the study were evaluated by persons associated with the UGDP and representatives of NIAMDD. The Food and Drug Administration was not involved in the planning, inception, or design of the UGDP study. The study was funded by NIAMDD as part of its responsibility to support research in the field of diabetes and not with any specific regulatory objective in mind.

5. The UGDP has been and still is funded by 13 grants from this Institute. A copy of the Coordinating Center grant and a grant for one of the 12 clinics are attached as Exhibits 2 and 3 respectively. Applications from the Coordinating Center and the 12 participating clinics of the UGDP were received and reviewed by a special review committee of NIAMDD during 1960-63 that recommended approval on the basis of merit. The UGDP was also recommended by the National Advisory Arthritis and Metabolic Diseases Council at its meetings in June, 1960, June, 1961, June, 1962, and June, 1963. The Council provided the recommendations for approval necessary by law for funding of the research by NIAMDD.

6. The 13 research grants of the UGDP came up for consideration of renewal for continuation of the study in 1966. They were first reviewed by a Special Study Section (a panel of experts in diabetes research and treatment) of

NIH in September 1966 and by the National Advisory Arthritis and Metabolic Diseases Council in November 1966. After careful analysis and discussion, both groups recommended approval. Support of the study by NIAMDD continued.

7. The 13 grants again came up for review in 1971. A Special Study Section of NIH met in July and, on the basis of merit, again recommended approval. The Council, at its meeting in November 1971, also recommended approval and rated the UGDP study of "High Program Relevance". This rating was, in effect, a direction to Institute staff to provide financial support for the UGDP grants regardless of the competition of other applications for funds available for research grants.

8. Continuing studies by the cooperating clinics and analysis of the data by the Coordinating Center will be supported until August 31, 1977.

9. The UGDP raw data (e.g., patient charts and forms) are the property of the individual investigators and the Coordinating Center and are not owned by NIAMDD. Furthermore, it is not the normal practice of NIH or this Institute to require grantees to submit their raw data for review and, in fact, submission of raw data to the institute is extremely rare. Management of the day-to-day operations of grant-supported activities is the responsibility of the grantee. Supervision of the grantee's funded activities by this Institute is generally limited to review of periodic reports submitted by the grantee. (45 CFR §§ 74.80, 74.82). Due to the large number of research grants outstanding—currently approximately 1800—it would not be physically possible for the Institute to subject raw data, if submitted, to critical review, and to require submission of the raw data of the UGDP study would have been an extraordinary requirement. It is the practice to evaluate applications for renewal grants on the basis of progress reports and final reports submitted to NIH. This practice was followed with respect to the UGDP grants. No specific provision of the

UGDP grants required submission of raw data to the Department of Health, Education, and Welfare. Pursuant to 45 CFR § 74.23, officers or employees of the Department could obtain access to the raw data for purposes of audit inspection and copying if access is deemed pertinent to the grant. The raw data which are the subject of this case have never been seen by, or been in the possession of, any officer or employee of the National Institutes of Health. I have been advised, and on information and belief so state, that the documents comprising the raw data currently number in the millions, possibly as many as 55 million, and contain information that would identify the patients.

10. The National Institute of Arthritis, Metabolism, and Digestive Diseases supported by contract a study of the biometric aspects of the design, conduct and analysis of the trial of the University Group Diabetes Program as well as other trials of oral hypoglycemic agents. This study of the biometric aspects of these trials was conducted by a committee of the Biometric Society, a private professional society. The contract did not require either that the committee seek access to the raw data or that any raw data that may be studied be transmitted to the Institute. At the conclusion of the study, the committee did not submit to the Institute any raw data pertaining to the University Group Diabetes Program, or any other raw data. The results of the committee study were published in the Journal of the American Medical Association.

/s/ G. DONALD WHEDON
G. Donald Whedon, M.D.

Subscribed and sworn to before me, a Notary Public, in and for the State of Maryland this 18th day of November, 1975.

/s/ SALLY A. LINN
Sally A. Linn
Notary Public

My commission expires July 1, 1975.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, HENRY DOLGER, HOLBROOK S. SELTZER,
as they are members of the Committee on the Care of
the Diabetic, *Plaintiffs*,

v.

DAVID MATHEWS, Secretary of the Department of Health,
Education, and Welfare; THEODORE COOPER, Assistant
Secretary of Health, Department of Health, Education
and Welfare; ALEXANDER M. SCHMIDT, Commissioner
of the Food and Drug Administration. G. DONALD
WHEDON, Director of the National Institute of Arth-
ritis, Metabolism, and Digestive Diseases; CHRISTIAN R.
KLIMT, *Defendants*.

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION
FOR SUMMARY JUDGMENT**

Now come plaintiffs in the above-entitled action and oppose the Government defendants' Motion to Dismiss or In The Alternative for Summary Judgment and offer in support thereof the Memorandum of Points and Authorities accompanying plaintiffs' Complaint filed September 30, 1975 (See in particular, pages 19-25); and the Memorandum of Points and Authorities submitted herewith.

Plaintiffs respectfully request a hearing on this Motion.

Respectfully submitted,

CHAYET AND SONNENREICH, P.C.

By:

NEIL L. CHAYET

HARVEY W. FREISHTAT

Attorneys for Plaintiffs

Six Fayette Street

Boston, Massachusetts 02116

Telephone No.: (617) 357-0202

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, *et al.*, Plaintiffs

v.

DAVID MATHEWS, *et al.*, Defendants

MOTION FOR SUMMARY JUDGMENT

Plaintiffs in the above-captioned matter respectfully move the Court to grant summary judgment in their favor on the grounds that no issue of material fact exists and they are entitled to judgment as a matter of law. Rule 56, Federal Rules of Civil Procedure.

In support of their motion for summary judgment and in opposition to defendants' motion to dismiss and for summary judgment, plaintiffs submit herewith a memorandum of points and authorities and exhibits.

Plaintiffs respectfully request a hearing on the within Motion.

Respectfully submitted,

CHAYET AND SONNENREICH, P.C.

By:

NEIL L. CHAYET

HARVEY W. FREISHTAT

Attorneys for Plaintiffs

Six Fayette Street

Boston, Massachusetts 02116

Telephone No.: (617) 357-0202

EXHIBIT A
STATEMENT OF
ANGELA J. BOWEN, M.D.
BEFORE

THE FOOD AND DRUG ADMINISTRATION
PUBLIC HEARING ON THE PROPOSED LABELING
FOR ORAL HYPOLYCEMIC DRUGS

AUGUST 20, 1975

My name is Angela Bowen. I practice medicine in Olympia, Washington. I am a reluctant witness here today because what I must say will complicate the lives of old friends and acquaintances. I have tried to avoid active participation in the controversy because I still number many of the investigators of the UGDP among my closest friends. My association with the UGDP began in 1963 and continued until 1970 when I resigned for reasons that will become apparent shortly.

The results of the study have been subjected to a variety of criticisms, usually on the scientific merit. If one were to judge the study simply on its published claims a seasoned investigator would marvel at how everything was done *exactly* as planned in the protocol. Most investigators will acknowledge that the final performance of a research project rarely approximates the initial plan, however well thought out. As a long time participant in the UGDP I can assure you that it didn't happen that way in this study either. I am referring now to the day to day conduct of the study.

This was unremittingly dull work and tended to be assigned to the most junior member of the pecking order, a position in which I found myself in those days. I therefore became well acquainted with the day to day drudge involved in such a study. It is the accurate performance of this daily drudge that holds the key to the strength or weakness of such a study. There were of course wide differences in its

performance in the different clinics. It was almost never done by the principal investigator, sometimes by third year medical students, sometimes by residents or other temporary personnel. Thus, differences in the maturity and quality of clinical judgment were apparent in evaluation of complications and side effects.

Certainly there was an honest attempt by the Principal Investigator to initially do everything by the book. But, as the tasks became shunted to the periphery, enthusiasm waned. Gathering of data was complicated by the long term nature of the study and the fact that six of the original twelve investigators left and were replaced at various points in the study. I have serious doubts as to the accuracy with which the data was collected in the various clinics.

For example, most investigators had a bias that control of blood sugar was not important. Some investigators were thus willing to let blood sugar levels get quite high without intervening with alternate treatment. Our group, on the other hand, felt that a normal blood sugar level was preferable to an abnormal one and we tended to prescribe alternate treatment fairly early if the study medication did not do the job—thus, our clinic had a fairly high number of people who were taken off study medication and managed by usual and customary means.

This may explain why the death rate was much lower at our center. These are just a few examples of problems I observed in the day to day conduct of the study. There are others.

An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "were the data that were gathered in the field accurately and honestly

recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstance was discussed at length. This ended with the demand from the New York delegates that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfeld and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators.

The situation was not improved when the Phenformin data continued to be unavailable. The reason was given that the coordinating center was overworked, the computer wasn't working well and finally that insufficient time had elapsed. These may have been valid reasons, but—they simply did nothing to reassure the skeptics among us that no collusion existed between USV and Dr. Klimt. As you

may have gathered, the UGDP was, for me, a very disillusioning experience.

As this matter progressed, it became increasingly difficult to voice legitimate scientific concerns, and the entire project began to assume a vendetta-like quality against the manufacturer of tolbutamide. For example, when the attached list of patients (See attachment A) was provided by Dr. Kenneth Kreins of Cincinnati to illustrate his anxiety that the patients in the tolbutamide treatment group were very ill from causes not related to their diabetes, he was interrupted by the Chairman (Thaddeus Prout, M.D.) and not permitted to proceed.

Several subsequent meetings were held where this matter was discussed. The meeting at Jamestown during the following year led to a vote being taken about whether the evidence was strong enough to warrant discontinuing tolbutamide. Again the investigators were divided. There were demands by the program chairman (Dr. Max Miller) that complete unanimity be reached because otherwise the decision would not be viewed as seriously as he hoped it would be. This meeting was committed to tape in its entirety and will corroborate that feelings continued to run strong that dishonesty was a real possibility. My co-investigator requested from the coordinating center a printout of the data from our clinic to determine whether it agreed with our own data kept in the clinic. That request, like all other requests, was refused. The jealousy with which access to the data has been guarded to all who requested it is not reassuring. Dr. Reeves, my co-investigator, and I felt that we could not in good conscience attach our names to the conclusions proposed and finally released by the UGDP. We therefore resigned rather than do so. A year or so later the phenformin data became available and there was pressure from some investigators to drop it too. A representative from USV came to Olympia and alleged that he had been told by Dr. Klimt that we were told people who were most interested in seeing that phenformin was dropped from the study.

We, of course, no longer were involved in the study and certainly no voice in what was done about phenformin. One can only speculate why such charge might have been made by Dr. Klimt if in fact, it was made. This episode permanently fix in my mind the strong suspicion that a continuing relationship existed between USV and Dr. Klimt.

It is not my intent to make statisticians sound less honest than the rest of us. Unfortunately their language is not spoken by the many who must live by their decisions. It is possible that no dishonesty existed. It is equally possible that it did. But, since the FDA has assumed the role of final arbiter in this issue, the FDA should know for sure. It is unfortunate that the agency assumed the position of supporting the UGDP conclusions prior to their full scientific review. This has given the illusion of rigidity and some have suggested that Dr. Klimt was instrumental in this approval since he was also working here at the FDA when that approval was given. These are simply troublesome questions that nag at some of us and I would be very happy if they could be explored and proven to be groundless. The cloud surrounding this study must now either be dispelled or confirmed. Those of us who live in the provinces and work on the front lines of patient care have come in recent years to feel somewhat abandoned by the FDA. It has appeared more and more to be taking the position that practicing physicians are not to be trusted with medications or pharmacologic decisions and that these decisions are best made by the Commissioner and transmitted directly to the patient via the wire services. Now this may not actually be the position of the agency but it is how it is perceived in the field.

What of the patient? How does he fare when decisions are made regarding his therapy by some distant committee of experts? I have pulled from my files the case of one such patient and could have brought a dozen others, to illustrate what can happen under such circumstances. This patient was one of the UGDP patients from the Seattle clinic who

had been treated with Phenformin and was switched to placebo when Phenformin was discontinued from the study. She came down to Olympia requesting treatment, bringing with her letters from the investigator showing that her blood sugar had steadily increased from 133 fasting to 321 after being managed with diet and placebo. Although she had protested that her skin was covered with a rash, she was developing dupuytren's contractures and had no energy to go about her daily tasks, she had been refused treatment. I prescribed treatment and her symptoms cleared straightaway. She again returned to the research clinic and was again put on placebo. Some months later she reappeared at my office with the same symptoms and a blood sugar of 289. I prescribed one of the oral agents and received in a few weeks the following letter:

(See Attachment B)

This demonstrates the numerous complications that come with aberrations in the blood sugar level that are not life threatening but certainly affect the patient's condition. Any practicing physician would have treated her as I did.

A few months ago I was privileged to hear one of the UGDP's principal investigators present data from a study of Glyburide. His last slide indicated what treatment the patients were transferred to when the Glyburide study was finished. Almost every patient was placed on oral agents. I could not, of course, resist public comment on his lack of faith in the UGDP conclusions, as evidenced by his clinical actions. After a few moments of silence he replied that, "yes he did have misgivings about the result" and that he believed normal blood sugars were preferable to abnormal ones and he planned to continue using oral agents.

What then are my recommendations to the FDA? I would like to see the Agency approach this exactly as they would if Upjohn or Ciba-Geigy or Pfizer came in claiming that their drugs prevented heart disease. You would demand proof and good quality case reports accurately reviewed.

The same should be done here. If there was the slightest indication that a clinical investigator had manipulated data to the drug company's benefit you would send an auditor to the scene and scrutinize the operation. That should be done here. Every case report in every clinic should be reviewed. The FDA must be above reproach.

If scientific issues are going to be discussed in the package insert, both sides should be presented, preferably as literature references and not as summaries prepared by the Agency. Dr. Simmons had said in communications to us that to present both sides of a controversy would "hopelessly confuse the practicing physician." Well, hopeless confusion is no stranger to the average practicing physician, she knows it well. I would then, like to see a little humility when these issues directly affect patient care as they do in this case. I would like to see fair balance in the package insert. The package insert seems a curious place to make alternative treatment suggestions. It is, you know, almost never seen by the physician. The pharmacist is usually the one who discards it unread into his basket. The suggestion that Insulin is the treatment of choice in this group of diabetics usually treated with oral agents is one that defies understanding. Such an experiment hasn't been done that showed any benefit to the patients longevity.

As long as the practice of medicine has existed the physician has had the right to select what he considers the proper therapy for the individual patient based on the most widely accepted scientific information available. Patients rely on their physicians for such advice. It is my fear, and that of many others that this important right is seriously threatened.

I fully understand how much courage it would require for the FDA to change its position on the UGDP at this late date, but I insist upon believing that it is capable of doing so if the evidence is compelling.

#50015 - J

This patient had severe generalized large vascular disease with previous strokes, myocardial infarctions and peripheral vascular insufficiency. One and one half years prior to death he was transferred to a chronic disease hospital and was lost to follow-up until five days prior to his death on 11/2/66. He claimed to have continued to take his AD medications, but this is doubtful. AD Rx was restarted, but the following day the patient was admitted to another hospital with bilateral flaccid paralysis, Cheyne-Stokes respirations and dysphagia and succumbed on 11/7/66 from presumed basilar artery thrombosis. I spoke with the attending physician and feel that the diagnosis is probably correct. During the terminal hospitalization the patient was receiving known tolbutamide.

#50017 - F

This patient with hypertensive and arteriosclerotic cardiovascular disease and angina pectoris was last seen in the UGDP Clinic on 5/26/65. He was admitted to the Cincinnati General Hospital on 5/30/65 with a cerebral infarct. Pneumonia supervened and the patient expired on 6/27/65. Autopsy revealed a fresh myocardial infarction, presumably the terminal event. During hospitalization AD treatment was discontinued and insulin substituted.

#50069 - L, F

This patient had known severe arteriosclerotic heart disease with angina pectoris and congestive heart failure. Three weeks prior to death chest x-rays revealed cardiomegaly and pulmonary congestion. Patient died in the emergency room at Cincinnati General Hospital on 8/22/66 with severe pulmonary edema. Although an electrocardiogram was not taken, the pulse rate was 140/minute rendering arrhythmia an unlikely diagnosis.

#50033 - M S

This patient was admitted to the Cincinnati General Hospital thirteen days prior to death because of hemiparesis. Angiograms revealed an aneurysm of the right internal carotid artery. Chest x-rays revealed a small left pleural effusion, possibly due to pulmonary embolus. The patient expired suddenly on 2/10/66. The immediate cause of death may have been rupture of the demonstrated aneurysm, cerebral thrombosis or pulmonary embolism.

#50008 - M B

This patient with long standing aortic stenosis previously suffered a left-sided CVI presumably due to cerebral embolism. Recovery was complete except for seizures for which she took dilantin. She was admitted to the hospital on 3/11/64 with severe dysphagia and dysarthria and died the following day. Post mortem revealed calcific aortic atherosclerosis, old myocardial infarction, mural thrombus, pneumonia and fresh embolization to a kidney. The probable cause of death was cerebral embolus. The brain was examined but the report cannot be found.

Died of perforation of the gall bladder on 10/16/66. No evidence of cardiovascular disease. Good adherence.

#50041 - V 1 F

Died 1/7/66 at Cincinnati General Hospital of bleeding gastric carcinoma and pneumonia. When last seen in clinic on 12/8/65 patient was taking his AB Rx plus digitalis.

#50050 - M

Died at home on 12/9/63 of metastatic carcinoma of colon. Last seen in UGDP Clinic on 9/11/63. Hospitalized at Cincinnati General Hospital on 9/27 to 10/7/63 at which time she was on known tolbutamide. No Rx after discharge.

#50037 - Goldie J

Patient with known ASHD, angina and CHF taking digitoxin, diuril and KCl, died at Cincinnati General Hospital on 11/17/64 of intestinal obstruction due to metastatic carcinoma of colon.

#50039 - Alice J.

Patient became a clinic treatment failure six months after admission because of severe symptoms of hyperglycemia. Insulin treatment was attempted but patient could not administer injections. Patient took known tolbutamide 1.5 gr. daily thereafter. This patient had paresis and gradually deteriorated becoming progressively disoriented and weakened physically. Terminally, she was confined to a nursing home where she developed pneumonia. The immediate cause of death was multiple pulmonary emboli from a venous thrombosis in the left calf.

#50005 - C le N

This patient had long standing severe ASHD with ECG changes of previous myocardial infarction and of auricular fibrillation. For several months prior to death he manifested severe congestive heart failure and was treated in the emergency room for this condition five days prior to death. He was seen in the Cardiac Clinic one day prior to death where it was noted that his prothrombin time was only 12%. The patient was receiving coumadin. The following day he was brought to the emergency room DCA. Death may have been caused by congestive heart failure, a myocardial infarction, an arrhythmia, or by a hemorrhage (cerebral or subintimal). Secondary to hypoprothrombinemia.

#50026 - B

This patient had no known history of cardiovascular disease. She was seen one week prior to death at which time she complained of left sided abdominal pain, nausea and vomiting. Gastro intestinal x-rays were ordered, but she died suddenly on 10/5/67 before the x-rays could be taken. This patient had dropped out of the UGDP Clinic in August of 1963 and, to our knowledge, took no anti-diabetic medications thereafter. Cause of death is unknown.

#50016 - N P H

This patient was last seen in the UGDP Clinic on 8/7/63 and died suddenly in Corbin, Kentucky on 10/30/63. Death certificate lists "heart failure", but this could not be substantiated. ECG and blood pressure were normal on 8/7/63. There was no prior evidence of cardiovascular disease. This patient took AB treatment from admission on 3/10/61 through 5/63 when she was made a treatment failure because of severe symptoms of hyperglycemia. She took 10-15 units of Lente insulin daily for the remaining five months of her life.. Cause of death is unknown.

ATTACHMENT B

Had a wonderful 3 weeks in
Honolulu.

From the Desk of—W. S. Howard

Dear Angela:

I wrote Dr. Nielson—Telling him how bad I had gotten and felt I needed a change in medicine, so had transferred to a new Dr. in Port A. & would be discontinuing with the Diabetic Clinic.

This is a copy of his reply. Is he trying in the 2nd ¶ to tell me pills only keep blood sugar down and doesn't really aid diabetes? I can't believe it. I feel like a new person since I went back on Dymelor. Rash gone—hands 90% improved etc.—& I was doing fine on the DBI at the clinic.

I didn't tell him I saw you or Dr. (?) name, and I'm not answering this letter or going back. I think he would have let me die. I told him of the numbness I had, knowing from past experience it was sugar acid in the blood—Dr. Hughes told me that, But Dr. Nielson didn't say a word.

Just wondered if you agree with ¶. 2. Thank you again.

Marjorie.

VIRGINIA MASON RESEARCH CENTER

*of the Virginia Mason Foundation for Medical Education
and Research*

1000 Seneca Street • Seattle, Washington 98101 •
MAin 4-1144, Area Code 206

January 22, 1974

Mrs. W. Seymour Howard
P.O. Box 267
Sequim, Washington 98382

Dear Mrs. Howard:

Thank you very much for your letter of January 16. As I look back over the blood sugar result we have had on you over the past several years, there has indeed been a gradual increase in the fasting levels. As you know, the study was designed to evaluate the effectiveness of various treatment programs on the progress of diabetes and, also, as you know, the study has shown that the active pills used in this study have resulted in no improvement in complication rates and, indeed, have resulted in some minor increase in death rate, as opposed to patients who were on the non-active pills. At the present time you have been on a non-active pill.

There is, to date, no evidence from the study that keeping the blood sugar normal with the pills in any way influences the progression of diabetes complications, and it was for that reason that we have continued to feel justified in not putting you on an active agent (such as the Dymelor you are now on) to bring your blood sugar back to normal.

This is a milestone study in American medicine, and it is extremely important that it be carried to completion—which should be within the next year. I would greatly appreciate, therefore, your returning to the study if you can see your way clear to do so. I realize there is a transporta-

tion problem, but we would be willing to pay your round-trip bus fare from Port Angeles for your visits every three months, and perhaps we could also arrange to make your visits at six-month intervals and combine a couple of examinations.

As you know, there are differing philosophies among physicians about the treatment of diabetes, and if your doctor is opposed to your continuing the study I would like very much to have the opportunity of communicating with him. Please let me know your present feelings and the name of your doctor so that I may write to him—provided you decide to return to the study.

Again, I would urge you that this is an extremely important study and at this point in time the dropout of even one patient is a significant deterrent to its successful completion.

Sincerely,

/s/ ROBERT L. NIELSEN
Robert L. Nielsen, M.D.

RLN:ps

FEDERAL REGISTER, VOL. 39, NO. 248—
TUESDAY, DECEMBER 24, 1974

§ 4.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD-483 and FD-2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 4.64, the Commissioner determines that they are subject to discretionary release pursuant to § 4.82.

(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 4.64. For example, an establishment inspection report is an investigatory record and thus subject to § 4.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 4.82.

§ 4.102 Court enforcement records.

(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has

an accurate copy of such a record or document, the person requesting a copy shall be referred to the court involved.

(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

§ 4.103 Correspondence.

(a) All correspondence to and from members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal Government and special government employees, is available for public disclosure.

(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., correspondence relating to an IND notice or an NDA in § 314.14(e)(7) of this chapter.

§ 4.104 Summaries of oral discussions.

(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of

the Federal government or special government employees, are available for public disclosure.

(b) Any such summary is available for public disclosure at the time that it is prepared by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., summaries of oral discussions relating to a food additive petition in § 121.51(h)(3) of this chapter.

(c) If more than one summary of an oral discussion exists in a Food and Drug Administration file, all such summaries shall be disclosed in response to any request for such summary.

§ 4.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance essays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

§ 4.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.

(a) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the responsible agency official:

- (1) Quarterly and annual reports of the agency.
- (2) External investigations or review of agency needs and performance.
- (3) Surveys, compilations, and summaries of data and information.
- (4) Consumer surveys.
- (5) Compliance surveys.
- (6) Compliance programs, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the program is completed.
- (7) Work plans prepared by Food and Drug Administration bureau, field offices, and other components, except that names of specific firms, the location, of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the plan is completed.

(b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:

- (1) Internal audits of agency needs and performance.

(2) Records relating to the internal planning and budget process.

(3) Legislative proposals or comments prior to submission to Congress.

§ 4.107 Food and Drug Administration manuals.

(a) All Food and Drug Administration staff manuals and instructions to staff that affect a member of the public are available for public disclosure. All and other similar data and information after deletion of:

- (i) Names and any information that would identify the person using the product.
- (ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of Part 4 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time that any one of the following events occurs:

- (1) The NADA has been abandoned and no further work is being undertaken with respect to it.
- (2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.

(3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NADA file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

PART 146—ANTIBIOTIC DRUGS FOR VETERINARY USE: PROCEDURAL AND INTERPRETATIVE REGULATIONS

9. In Part 146, by adding the following new section:

§ 146.16 Confidentiality of data and information in an investigational new animal drug notice and a new animal drug application file for an antibiotic drug.

(a) The rules established in §§ 135.33 and 135.33a of this chapter with regard to the confidentiality of an investigational new animal drug notice and a new animal drug application file shall apply to such notices and files for antibiotic drugs for new animal drug use.

(b) All records showing the Food and Drug Administration's testing of and action on a particular lot of a certifiable antibiotic drug for veterinary use are immediately available for public disclosure.

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

10. In Part 312, by adding new § 312.5 to read as follows:

§ 312.5 Confidentiality of data and information in an investigational new drug notice (IND).

(a) The existence of an IND notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file shall be handled in accordance with the provisions established in § 314.14 of this chapter for the confidentiality of data and information in new drug applications.

(c) Notwithstanding the provisions of § 314.14 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational new drug has been used a copy of any adverse reaction relating to such use.

PART 314—NEW DRUG APPLICATIONS

11. In Part 314:

a. By revising the heading and paragraph (b) of § 314.11 to read as follows:

§ 314.11 Master files.

• • • • •

(b) Section 301(j) of the act makes it an offense to divulge to unauthorized persons any information acquired from a new-drug application concerning any method or process that is a trade secret. Basic manufacturers sometimes submit data to the Food and Drug Administration in the form of so-called master files for the purpose of establishing the safety of ingredients that may be used in new drugs and authorize specified applicants to incorporate by reference such data in support of their applications. The confidentiality of such data shall be determined in accordance with Part 4 of this chapter and § 314.14. Because the applicant is legally responsible for the composition of the new drug and all its ingredients and may require information in the master file for judicial or administrative proceedings concerning the drug, the Food and Drug Administration will not withhold such information from the applicant when his need for it arises and he submits a written request for it. The Food and Drug Administration will inform the person who submitted the data of any such requests.

b. By adding new § 314.14 to read as follows:

§ 314.14 Confidentiality of data and information in a new drug application (NDA) file.

(a) For purposes of this section the "NDA file" includes all data and information submitted with or incorporated by reference in the NDA, IND's incorporated into the NDA, supplemental NDA's; reports under §§ 310.300 and 310.310 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NDA file shall be handled in accordance with the provisions of this section.

(b) The existence of an NDA file will not be disclosed by the Food and Drug Administration before an approvable letter has been sent to the applicant, unless it has previously been publicly disclosed or acknowledged. The Director of the Bureau of Drugs will maintain a list available for public disclosure of pending NDA's for which an approvable letter has been sent to the applicant.

(c) If the existence of an NDA file has not been publicly disclosed or acknowledged, no data or information in the NDA file are available for public disclosure.

(d) If the existence of an NDA file has been publicly disclosed or acknowledged before an approval letter has been sent to the applicant, no data or information contained in the file is available for public disclosure before such letter is sent but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an approval letter has been sent to the applicant for a pending NDA, the following data and informa-

tion in the NDA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in § 4.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NDA file. Such summaries do not constitute the full reports of investigations under section 505 (b)(1) of the act (21 U.S.C. 355(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:

(i) For an NDA approved prior to July 1, 1975, internal agency records that describe such data and information, e.g., a summary of basis for approval or internal reviews of the data and information, after deletion of:

(a) Names and any information that would identify patients or test subjects or the investigators.

(b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an NDA approved on or after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the approval letter is sent.

(a) The Bureau of Drugs may at an appropriate time prior to approval of the NDA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, revised by the Bureau.

(b) The Bureau of Drugs may prepare its own summary of such data and information.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 4.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.81 of this chapter.

(6) An essay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NDA file, in accordance with the provisions of Part 4 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time that any one of the following events occurs:

(1) The NDA has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the NDA is not appropriate, and all legal appeals have been exhausted.

(3) Approval of the NDA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the drug is not a new drug.

(5) A final determination has been made that the drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NDA file are not available for public disclosure unless they have been previously disclosed to the public as defined in §4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) The compilations of information specified in §4.117 of this chapter are available for public disclosure.

(i) For purposes of this regulation, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

12. In Part 431, by adding a new Subpart D to read as follows:

Subpart D—Confidentiality of Information

Sec. 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

Sec. 431.71 Confidentiality of data and information in an antibiotic drug file.

AUTHORITY: Pub. L. 90-23, 81 Stat. 54-56, as amended by 88 Stat. 1561-1585 (5 U.S.C. 552).

Subpart D—Confidentiality of Information

§ 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for an antibiotic drug shall be handled in accordance with the provisions established in § 431.71.

(c) Notwithstanding the provisions of § 431.71, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational antibiotic has been used a copy of any adverse reaction report relating to such use.

§ 431.71 Confidentiality of data and information in an antibiotic drug file.

(a) For purposes of this section, an "antibiotic drug file" includes all data and information submitted with or incorporated by reference in any form submitted pursuant to §§ 431.50 or 431.60, IND's incorporated into any such form, master files, and other related submissions. The availability for public disclosure of any record in the antibiotic drug file shall be handled in accordance with the provisions of this section.

(b) The existence of an antibiotic drug file will not be disclosed by the Food and Drug Administration before an approvable letter has been sent to the applicant, unless it has previously been publicly disclosed or acknowledged. The Director of the Bureau of Drugs will maintain a list

available for public disclosure of pending Forms 5 for which an approvable letter has been sent to the applicant.

(c) If the existence of an antibiotic drug file has not been publicly disclosed or acknowledged, no data or information in the antibiotic drug file is available for public disclosure.

(d) If the existence of an antibiotic drug file has been publicly disclosed or acknowledged before an approval letter has been sent to the applicant, no data or information contained in the file is available for public disclosure before such letter is sent, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange or important regulatory information with a foreign government.

(e) After an approval letter has been sent to the applicant for a pending antibiotic drug file, the following data and information in the NDA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 4.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(4) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.81 of this chapter.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 75-1608

PETER H. FORSHAM, *et al.*, *Plaintiffs*,

v.

DAVID MATHEWS, *et al.*, *Defendants*.

ORDER

Upon consideration of plaintiffs' motions for summary judgment and expedited relief, defendant Klimt's motion to dismiss and to quash service of process, federal defendants' motion to dismiss or in the alternative, for summary judgment, the Oppositions thereto, the memoranda of the parties in support thereof and in opposition thereto, and the entire record herein, the Court finds that (1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the National Institutes of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) (*See Affidavits of Theodore M. Cooper, M.D. and Donald Whedon, M.D., Federal Defendants' Motion to Dismiss or, in the alternative, for Summary Judgment*); (2) the raw data in question is the property of the individual investigators and UGDP study coordinating center and remains in the possession, custody and control of the UGDP study coordinating center (*See Affidavit of Donald Whedon, M.D., supra*); (3) neither the individual investigators nor the UGDP study coordinating center is an "agency" within the purview of the Freedom of Information

Act, 5 U.S.C. § 552¹; and (4) consequently, the raw data in issue are not "agency records" subject to the disclosure provisions of the Freedom of Information Act, 5 U.S.C. § 552(B).

It is, accordingly, by the Court this 1st day of February, 1976,

ORDERED that plaintiffs' motion for summary judgment should be, and the same is hereby, denied. And it is further

ORDERED that defendants' motions to dismiss should be, and the same are hereby, granted.²

/s/ HOWARD F. CORCORAN
Howard F. Corcoran
Judge

¹ For purposes of the FOIA, an "agency" includes "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." 5 U.S.C. § 552(e).

² The remaining motions for expedited relief and to quash service of process are denied as moot.

UNITED STATES COURT OF APPEALS

For the District of Columbia Circuit

Washington, D.C. 20001

August 19, 1977

Leonard Schaitman, Esquire
 Appellate Section
 Civil Division
 U.S. Department of Justice
 Washington, D.C. 20530

Re: No. 76-1308—*Forsham v. Califano, et al.*

Dear Mr. Schaitman:

The Court has directed me to write to you to request that the Secretary of the Department of Health, Education and Welfare file in this Court an original and three certified copies of the Department's Order of July 25, 1977, suspending approval of new drug applications for Phenformin. I suggest that these materials be delivered to my office (Room 5413) to facilitate their transmittal to the Court.

It will be appreciated if the requested documents could be submitted within ten (10) days from the date of this letter.

Very truly yours,

/s/ GEORGE A. FISHER
 George A. Fisher, Clerk

GAF/kae

cc: Anthony J. Roccograndi, Esquire
 Mary Elizabeth Kruz, Esquire

UNITED STATES DEPARTMENT OF JUSTICE

Washington, D.C. 20530

August 29, 1977

Telephone: 202-739-3418

Mr. George A. Fisher
 Clerk, United States Court of Appeals
 for the District of Columbia Circuit
 United States Courthouse
 Room 5423
 3rd & Constitution Avenue, N.W.
 Washington, D.C. 20001

Re: Peter H. Forsham, et al. v. Joseph A. Califano, Jr.,
 et al. (No. 76-1308, C.A.D.C.)

Dear Mr. Fisher:

In accordance with your request of August 19, 1977, we are hand-delivering to you four certified copies of the order of July 25, 1977 of the Department of Health, Education and Welfare, suspending approval of new drug applications for Phenformin.

A copy of this letter and of the order are being sent to other counsel in the case.

Very truly yours,

/s/ MICHAEL KIMMEL
 Michael Kimmel
 Attorney, Appellate Section
 Civil Division

Enclosures:

cc: Anthony J. Roccograndi, Esq.
 Chayet & Sonnenreich, P.C.
 6 Fayette Street
 Boston, Massachusetts 02116

Ms. Mary Elizabeth Kurz
 Assistant Attorney General
 Lobby Level
 201 West Preston Street
 Baltimore, Maryland 21201

APPENDIX A: APPELLANT'S MOTION FOR REHEARING
OF SEPT. 13, 1977

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Civil Action No. 76-1308

PETER H. FORSHAM, *et al.*, Appellants

v.

JOSEPH A. CALIFANO, JR., *et al.*, Appellees

MOTION FOR FURTHER HEARING

Come the appellants in the above-captioned matter and state as follows:

1. At oral argument of this matter on December 2, 1976, appellees stated through their counsel that the Food and Drug Administration (FDA) was undertaking an audit of the raw data of the University Group Diabetes Program (UGDP). These data were the records sought by appellants pursuant to the Freedom of Information Act (5 U.S.C. 552). Appellees further stated that copies of all data which came into FDA's possession during the course of this audit would be provided to appellants forthwith.

2. On February 9, 1977, in response to appellants' request, the FDA again agreed to send appellants copies of all UGDP documents which had come into its possession during the UGDP audit. However, the FDA also informed appellants that most of the UGDP audit had been conducted by making abstracts of the data at the UGDP Coordinating Center rather than by annually copying the data or ordering transmission of the data to the FDA for internal audit. As a result, the FDA notified appellants that the documents are not as informative as you might like." (Appendix A).

3. On May 5, 1977, appellants renewed their request for "all documents including the raw data and any abstracts thereof that were gathered as a result of the UGDP audit." (Appendix B)

4. On May 23, 1977, appellants received copies of what purported to be *all* materials gathered by the FDA during the course of the UGDP audit. (Appendix C)

5. On information and belief, appellants state that the FDA has additional documents which have come into its possession during the UGDP audit which have not been provided to appellants. Failure to provide these documents violates the provisions of the Freedom of Information Act (5 U.S.C. 552) as well as the specific assurances made by appellees during oral argument that such data would be provided to appellants forthwith.

WHEREFORE, appellants move in accordance with Rule 29 of the Federal Rules of Appellate Procedure and Rule 6 of the U.S. Appeal D.C. Circuit Rules, as follows:

1. That a hearing be convened wherein appellees can explain why appellants have not been provided copies of all documents which came into the possession of appellees during the course of the UGDP audit.

2. For such other and further relief as this Court may deem just and proper.

Respectfully submitted,

/s/ NEIL L. CHAYET

Neil L. Chayet

/s/ HARVEY W. FREISHTAT

Harvey W. Freishtat

Sept. 13, 1977

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., *Plaintiffs-Appellants*,

v.

JOSEPH A. CALIFANO, JR., Secretary of Health, Education
and Welfare, et al., *Defendants-Appellees*.

**APPELLEES' OPPOSITION TO
APPELLANTS' MOTION FOR FURTHER HEARING**

Appellants have moved for a further oral hearing in the above-captioned case, alleging that a hearing is needed so that "appellees can explain why appellants have not been provided copies of documents which came into the possession of appellees during the course of the UGDP audit" (Motion, p. 2). Appellants allege, "on information and belief," that FDA has "additional documents which have come into its possession during the UGDP audit which have not been provided to appellants" (Motion, p. 2).

Appellees oppose this motion, for the following reasons:

1. As indicated in the May 20, 1977 letter from Mr. Mark A. Elengold, Freedom of Information Officer, Bureau of Drugs, Food and Drug Administration, to counsel for appellants (Appendix C to appellants' motion), the FDA has furnished appellants' counsel with certain records, with "minor deletions." The letter explains:

In the judgement [*sic*] of the Food and Drug Administration the information deleted does not fall within the scope of your request and, in any case, is not required to be disclosed under the Freedom of Information Act. If, however, you do desire to review the deleted material, please make an additional request.

If the agency should then deny you this information, you would have the right to appeal such denial to the Department of Health, Education, and Welfare.

The correspondence attached to appellants' motion does not indicate that any further written request was made by appellants for production of the "minor deletions" in question, or that any other written request for records has been made since May, 1977.¹

Appellants' appropriate remedy, if they believe that FDA is in physical possession of additional records available under the Freedom of Information Act (not already furnished them pursuant to their request), is to make an administrative request in writing, and, if dissatisfied, to pursue their normal administrative and district court remedies.

The position of the government in this case is that, to the extent FDA should obtain "agency records" in the course of its audit of UGDP, and to the extent such records are not exempted from disclosure, such records will, upon written request, be provided to appellants (and to any other member of the public) in the normal course.² Appel-

¹ Our own telephone inquiries to officials of FDA have confirmed that appellants have made no further written request for records pertaining to the UGDP audit. We understand that a recent oral request for certain records was made by appellants; we assume that that request will be confirmed in writing so that it can be processed in the normal course.

Appellants' counsel apparently communicated directly with officials of the Department of Health, Education and Welfare, or FDA, without bothering to inform counsel for the government in this case until filing the instant motion.

² This is the gist, if not the precise language, of what undersigned counsel for the government, Michael Kimmel, recalls stating at the oral argument of last December. See our brief at p. 30 n.41; 21 C.F.R. Pt. 20; *Tuchinsky v. Selective Service System*, 418 F.2d 155, 158 (C.A. 7, 1969).

lants are not entitled to special privileges not afforded other members of the public. They must make a "request" for existing records, 5 U.S.C. 552(a)(3), and they must pursue the normal remedies if disputes should arise.

2. The legal issue involved in this appeal pertains to records *not* in the possession of HEW or its constituent agencies, i.e., the general and complete raw data of the UGDP. Any disputes concerning data or records which at the present time are in the possession of HEW or FDA, or which are alleged to be in the possession of HEW or FDA, are separable from the present lawsuit, and should be resolved through the regular procedures.

Accordingly, appellants' motion for a further hearing should be denied.

We are authorized to state that counsel for Dr. Christian R. Klimt, the State appellee, concurs in this opposition.

Respectfully submitted,

/s/ LEONARD SCHAITMAN
Leonard Schaitman, 202-739-3321

/s/ MICHAEL KIMMEL
Michael Kimmel, 202-739-3418
Attorneys, Appellate Section,
Civil Division,
Department of Justice,
Washington, D.C. 20530.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Civil Action No. 76-1308

PETER H. FORSHAM, ET. AL., *Appellants*

v.

JOSEPH A. CALIFANO, JR., ET AL., *Appellees*

**ADDITIONAL ALLEGATIONS TO APPELLANTS' MOTION
FOR FURTHER HEARING OF SEPTEMBER 13, 1977**

Come the appellants in the above-captioned matter and due to developments ensuing since their Motion for Further Hearing of September 13, 1977 (Appendix A attached), make the following additional allegations to that motion:

1. On October 5, 1977, an evidentiary hearing was convened under 21 U.S.C. 355(e) pursuant to the Food and Drug Administration (FDA) Notice of May 6, 1977 (42 F.R. 23170) concerning proposed withdrawal of approval of the New Drug Application (NDA's) for phenformin hydrochloride. Phenformin hydrochloride is an oral hypoglycemic agent whose actions were studied by the University Group Diabetes Program (UGDP) study.

2. The aforementioned hearing was conducted on an expedited basis under 21 U.S.C. 355(e) due to an imminent hazard suspension of the NDA's for phenformin hydrochloride by the Secretary of Health, Education, and Welfare. One of the four express bases supporting the Secretary's decision to suspend was the UGDP study. (Secretary's Order at p. 38, Appendix B)

3. The Food and Drug Administration's Bureau of Drugs introduced published reports of the UGDP study as evidence at the phenformin hydrochloride administrative hearing. A Bureau of Drugs witness described the UGDP study

data as the best evidence available related to the issues of the hearing. (See Appendix C)

4. All evidence relied upon by a participant to the hearing must be submitted prior to the hearing in accordance with 21 C.F.R. 12.85. The FDA's Bureau of Drugs failed to submit any supporting data from the UGDP study, despite the fact that it relied upon such study. However, upon further requests during the administrative hearing by the Committee for the Care of the Diabetic (CCD), of which appellants are members, counsel for the FDA's Bureau of Drugs indicated a lack of knowledge on the availability of UGDP supporting data. Administrative Law Judge Daniel J. Davidson ordered Bureau of Drugs counsel to obtain all UGDP documents and data in the possession of the FDA. (See Appendix D) In response, counsel for Bureau of Drugs submitted on October 6, 1977, several documents relating to the UGDP. These documents contain fractional portions of UGDP information, not data, gleaned from a small percentage of the patient population, the subject of a limited audit of the UGDP by FDA. The Bureau of Drugs represented that these were all the materials gathered by the FDA during the course of its UGDP audit.

5. During the phenformin hydrochloride administrative hearing, the UGDP information surrendered on October 6, 1977 was analyzed by witness Samuel Beaser, M.D. The one and only incident of a phenformin related death attributed to lactic acidosis reported by the UGDP in its published report was examined and compared to one of the documents (autopsy report) turned over by FDA, pursuant to CCD's request and Judge Davidson's order. Dr. Beaser's uncontroverted testimony demonstrated that the death was due to other disease processes and, in light of the disease process, phenformin hydrochloride therapy was contraindicated. (See Appendix E)

The inclusion of this patient in the UGDP's patient population was a violation of the rules under which the UGDP data purportedly was gathered. (See Appendix E at pp. 53-54) The improper attribution of this patient's death to phenformin hydrochloride therapy provided the one piece of information on which statistics of fatal side-effects for this drug were based. Extrapolations from this flawed data were then applied by Secretary Califano to justify suspension of phenformin hydrochloride prior to utilizing normal administrative proceedings. The importance of this error is demonstrated by the fact that FDA's own witness certified that the UGDP represented the best evidence available at the phenformin administrative hearing. (See Appendix C)

6. The complete, uncontroverted discrediting of the one piece of UGDP data available and pertinent to the phenformin administrative hearing confirms the opinion of a large body of the scientific community that the entire UGDP study is seriously flawed. The confirmation emphasizes the need for availability of all the UGDP raw data for public review and analysis. Public policy requires a lowering of the barriers the FDA has constructed to delay, if not prevent, an impartial analysis of the raw data.

7. The recent developments at the phenformin hydrochloride administrative hearings provide evidence of the following:

- The FDA's lack of good faith by (1) representing to this Court in December of 1976 that all materials gathered by the FDA during the UGDP audit would be supplied to appellants; and (2) representing to appellants in May of 1977 that all materials gathered by the FDA during the UGDP audit had been supplied to appellants;
- The FDA's clear exercise of dominion and control over all the UGDP raw data as demonstrated by its

retrieval of raw data from one central location, principally through use of computer printouts; and,

- The compelling public interest in independent scientific review of the UGDP data, especially in light of the reliance of the FDA on the UGDP for decision-making affecting millions of diabetic patients and the impeachment of the UGDP's accuracy as demonstrated by a critical examination at the administrative hearing of documents—not even the raw data—which contradicted the published reports of the UGDP summaries and conclusions. The “tip of the iceberg” has provided a concrete basis—not mere speculation—to mandate that, at a minimum, the raw data reviewed by FDA in its audit must be objectively analyzed to resolve this issue once and for all.

WHEREFORE, appellants move in accordance with Rule 27 of the Federal Rules of Appellate Procedure and Rule 6 of the U.S. Appeals, D.C. Circuit Rules as follows:

1. That a hearing be convened wherein appellees can explain why appellants have not been provided copies of all data and related documents which came into the possession of appellees during the course of the UGDP audit.

2. For such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Neil L Chayet

Harvey W. Freishtat

Chayet and Sonnenreich, P.C.
600 New Hampshire Ave., N.W.
Suite 720
(202) 965-4150

October 26, 1977

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, *et al.*, *Plaintiffs-Appellants*,

v.

JOSEPH H. CALIFANO, JR., Secretary of Health, Education
and Welfare, *et al.*, *Defendants-Appellees*.

and

CHRISTIAN R. KLIMT, Director of Clinical Investigation,
University of Maryland School of Medicine, and Di-
rector, Coordinating Center, University Group Diabetes
Program (UGDP), *Defendant-Appellee*.

**FEDERAL APPELLEES' RESPONSE TO
APPELLANTS' "ADDITIONAL ALLEGATIONS"**

Appellants have submitted to the Court various evidentiary materials from an on-going administrative proceeding of the Food and Drug Administration under 21 U.S.C. 355(e). The purpose of that proceeding is to hear evidence and argument relevant to the withdrawal of FDA's approval of new drug applications (NDA's) for Phenformin. 42 Fed. Reg. 23170. None of the evidentiary materials submitted to this Court by appellants is in the record on appeal before this Court. F.R. App. P. 10(a).

Appellants have submitted these materials in support of their September 13, 1977 motion for a further oral hearing on their right of access to UGDP audit data in the possession of FDA. We have opposed that motion in our Opposition of September 23, 1977. As we then pointed out, the present appeal is concerned with appellants' action to compel disclosure of the general and complete raw data of the

UGDP. The appeal is not concerned with that portion of the UGDP data which FDA has since obtained in the course of its audit. Appellants' proper remedy as to the latter is to submit a written request to the FDA, in accordance with FDA regulations, 21 C.F.R. Pt. 20, if they believe that they have not already been supplied with all non-exempted records obtained by FDA in the course of its audit. 5 U.S.C. 552(a)(3).

We categorically reject appellants' unfounded allegation of "lack of good faith" by the government (p. 4 of appellants' submission). We also strongly oppose appellants' attempt to continue to argue their appeal in this case by making charges of various kinds in connection with an ongoing administrative proceeding in another case, the Phenformin proceeding. Appellants have no right to make their appeal in an Information Act case a general forum for their arguments in an FDA withdrawal of approval proceeding, or a springboard for gathering of evidence in that proceeding. See *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975); our main brief, pp. 13-14. Cf. *Ditlow v. Schultz*, 170 U.S. App. D.C. 352, 357, 517 F.2d 166, 171 (1975).¹

¹ We make no attempt here to argue the merits or sufficiency evidence justifying any withdrawal of approval of Phenformin. That issue is simply not before this Court. It is before the FDA. If appellants believe that more than the published results of particular studies is needed in order to justify withdrawal of approval of Phenformin, they should make that argument to the FDA in the Phenformin proceeding, where it can be properly considered. 21 C.F.R. 12.89, 314.200(c)(3).

Appellants' September 13, 1977 motion for a further oral hearing should be denied, and their "additional allegations" should be stricken.

Respectfully submitted,

/s/ LEONARD SCHAITMAN
Leonard Schaitman, 202-739-3321

/s/ MICHAEL KIMMEL
Michael Kimmel, 202-739-3418
Attorneys,
Civil Division, Appellate Section,
Department of Justice,
Washington, D.C. 20530.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

SEPTEMBER TERM, 1977

Civil Action 75-1608

No. 76-1308

PETER H. FORSHAM, *et al.*, Appellants

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of
Health, Education and Welfare, *et al.*

BEFORE: Bazelon, Chief Judge; Leventhal and MacKin-
non, Circuit Judges

ORDER

Filed Nov. 16, 1977

It is ORDERED by the Court, *sua sponte*, that the parties to
this appeal are directed to file supplemental memoranda, on
or before December 5, 1977, addressing the following ques-
tions:

(1) What impact, if any, do the order of Secretary
Califano of July 25, 1977 suspending new drug appli-
cations of Phenformin and the subsequent hearings
have on the status of this case?

(2)(a) Have the raw data of the UGDP study been
made available to appellants, or is it likely that these
data will be made available to appellants in the foresee-
able future, either in connection with the pending post-
suspension proceedings on Phenformin or otherwise?

(2)(b) If so, will that moot the case?

(3) Should this Court remand the case to the district
court for further findings in connection with either
question (1) or (2)?

For the Court:

GEORGE A. FISHER, Clerk

/s/ By: ROBERT A. BONNER

Robert A. Bonner

Chief Deputy Clerk

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, *et al.*, Plaintiffs-Appellants,

v.

JOSEPH A. CALIFANO, JR., Secretary of Health, Education
and Welfare, *et al.*, Defendants-Appellees
(Federal appellees),

and

CHRISTIAN R. KLIMT, Director of Clinical Investigation,
University of Maryland School of Medicine, and Di-
rector, Coordinating Center, University Group Diabetes
Program (UGDP), Defendant-Appellee
(State appellee)

**SUPPLEMENTAL MEMORANDUM OF CHRISTIAN KLIMT
RESPONDING TO THE COURT'S ORDER OF NOVEMBER 16, 1977**

By Order dated November 16, 1977, this Court ordered
defendants to file supplemental memoranda addressing
three questions. This Memorandum addresses each question
seriatim.

(1) What impact, if any, do the order of Secretary
Califano of July 25, 1977 suspending new drug appli-
cations of Phenformin and the subsequent hearings
have on the status of this case?

Defendant-Appellee Klimt submits that Mr. Califano's
suspension of new drug applications of Phenformin and
the subsequent hearings have no direct impact on the status
of this case for the reason that administrative proceedings
are separate and distinct from proceedings under the Free-
dom of Information Act. *See Renegotiation Board v. Ban-*

nercraft Clothing Co., Inc., 415 U.S. 1 (1974). Indeed Plaintiffs-Appellants' rights under this Act are "neither increased nor decreased" by separate proceedings. *N.L.R.B. v. Sears, Roebuck & Co.*, 421 U.S. 132, 143, ftm. 10 (1975).

(2)(a) Have the raw data of the UGDP study been made available to appellants, or is it likely that these data will be made available to appellants in the foreseeable future, either in connection with the pending post-suspension proceedings on Phenformin or otherwise?

Defendant-Appellee Klimt states that as Director of the Coordinating Center of the UGDP and as custodian of the data in question, he has not made available to Plaintiffs-Appellants any of the data requested in this proceeding and further that the UGDP Coordinating Center does not intend to make this data available to Plaintiffs-Appellants. It is Defendant-Appellee Klimt's position that the raw data requested by Plaintiffs-Appellants is the property of the UGDP, and not of the federal government, and therefore is not subject to production upon Plaintiffs-Appellants' request, neither under the Freedom of Information Act (see Appellants' Brief, heretofore filed in this case) nor under Maryland Law (See Maryland Annotated Code, Article 76A, § 3(b)(iii); 3(c)(i) and (vii). It should be noted, however, that the FDA did undertake a limited audit of the UGDP study and did obtain certain of the raw data in question. Whether or not any or all of the data so obtained by the FDA has been turned over to Plaintiffs-Appellants is unknown to Defendant-Appellee Klimt.

Even if Plaintiffs-Appellants were to obtain some or all of the data from the FDA as a result of the Phenformin proceedings, most of the data would still be unavailable since the FDA has only gained access to a limited amount of the raw data through its audit. Furthermore, Phenformin was only one of the drugs studied by the UGDP.

Accordingly, Plaintiffs-Appellants' request for data relating to Tolbutamide, the principle drug under study by the UGDP, would remain outstanding.

(2)(b) If so, will that moot the case?

It is Defendant-Appellee Klimt's understanding that the FDA has no present intention to seek through audit any additional raw data from the UGDP. In view of this fact and since Defendant-Appellee Klimt has no present intention of releasing the raw data to Plaintiffs-Appellants, it is Defendant-Appellee Klimt's position that the present appeal will not become moot.

(3) Should this Court remand the case to the district court for further findings in connection with either questions (1) or (2)?

In view of Defendant-Appellee Klimt's response to questions 1 and 2, Defendant-Appellee Klimt submits that no useful purpose would be served by a remand.

Respectfully submitted,

/s/ FRANCIS B. BURCH
Francis B. Burch
Attorney General of Maryland

/s/ DAVID H. FELDMAN
David H. Feldman
Assistant Attorney General

/s/ MARY ELIZABETH KURZ
Mary Elizabeth Kurz
Assistant Attorney General
12th Floor
One South Calvert Building
Baltimore, Maryland 21202
Attorneys for Defendant-Appellee
Dr. Christian R. Klimt

I HEREBY CERTIFY that on this 1st day of December, 1977, copies of the foregoing Supplemental Memorandum of Christian Klimt Responding to the Court's Order of November 16, 1977 were mailed postage prepaid, to Neil L. Chayet, Esq., Harvey W. Freishtat, Esq. and Chayet & Sonnenreich, P.C., 6 Fayette St., Boston, Massachusetts 02116, Attorneys for the Plaintiffs-Appellants and to the Honorable Griffin Bell, United States Attorney General.

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., *Plaintiffs-Appellants*,

v.

JOSEPH A. CALIFANO, JR., Secretary of Health, Education
and Welfare, et al.,

Defendants-Appellees (Federal appellees),

and

CHRISTIAN R. KLIMT, Director of Clinical Investigation,
University of Maryland School of Medicine, and Direc-
tor, Coordinating Center, University Group Diabetes
Program (UGDP),

Defendant-Appellee (State appellee).

**SUPPLEMENTAL MEMORANDUM OF THE FEDERAL
APPELLEES RESPONDING TO THE COURT'S ORDER OF
NOV. 16, 1977**

By order of November 16, 1977, the Court (Chief Judge Bazelon, and Circuit Judges Leventhal and MacKinnon) directed the parties to file supplemental memoranda addressing four questions, as follows:

- (1) What impact, if any, do the order of Secretary Califano of July 25, 1977 suspending new drug applications of Phenformin and the subsequent hearings have on the status of this case?

The Secretary's July 25, 1977 order suspending new drug applications for Phenformin, and the subsequent administrative hearings, have no impact on the status of this case. That is because appellants are suing in this case under the Freedom of Information Act, and their rights under

the Information Act are "neither increased nor decreased" by the pendency of related administrative proceedings. *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975).

Nor is there any certainty (or likelihood) that appellants will obtain access to all the data they seek in this case as a result of the Phenformin proceedings.¹

Finally, nothing in the Phenformin order or in the Phenformin proceedings has any legal or material effect on the proper resolution of the underlying issue in this case (whether the general UGDP raw data are "agency records" under the Freedom of Information Act).²

- (2)(a) Have the raw data of the UGDP study been made available to appellants, or is it likely that these data will be made available to appellants in the foreseeable future, either in connection with the pending post-suspension proceedings on Phenformin or otherwise?

The Food and Drug Administration did obtain a small portion (quantitatively) of the UGDP data in the course of its recent audit of the UGDP; this portion (except patient-identifying information) has been made available to appellants (and to other interested persons). However, the vast bulk of the raw data of the UGDP study are still in the exclusive possession of the UGDP Coordinating Center (in the custody of State appellee Klimt). These remaining UGDP raw data are neither possessed by nor owned by any federal agency, hence are not "agency records" so far

¹ Furthermore, as pointed out in our main brief (pp. 3-4), Phenformin was only one of the drugs subject to the UGDP study. The principal drug under study was Tolbutamide.

² The fact that the FDA has obtained through the Secretary's auditing rights some of the UGDP data (which data have been made a part of the administrative record in the Phenformin proceeding) does not cause the remainder of the UGDP raw data (which was not obtained) to become "agency records."

as the federal appellees are concerned; and have not been made available to appellants by the UGDP Coordinating Center. Whether or not the UGDP Coordinating Center will make these data available in the foreseeable future to appellants is unknown by the federal appellees. Based on past experience it appears unlikely that the UGDP Coordinating Center will make the data available to appellants.

- (2)(b) If so, will that moot the case?

Assuming that the general and complete UGDP raw data are not made available to appellants by the UGDP Coordinating Center, as appears to be the case, the present appeal will not become moot.

The FDA has no present intention of obtaining the remaining portions of the UGDP raw data through the auditing rights of the Secretary. Therefore it is unlikely that the present appeal will become moot by virtue of any possible further auditing of the UGDP raw data by FDA.

- (3) Should this Court remand the case to the district court for further findings in connection with either question (1) or (2)?

If there are no genuine issues of material fact as to the correctness of the foregoing statements, no useful purpose would be served by a remand. The federal appellees believe that there are no genuine issues of material fact.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of December, 1977, I served the foregoing Supplemental Memorandum for the Federal Appellees by causing copies to be mailed to:

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UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Civil Action No. 76-1308

PETER H. FORSHAM, et al., *Appellants*

v.

JOSEPH A. CALIFANO, JR., et al., *Appellees*

**SUPPLEMENTAL MEMORANDUM OF POINTS AND
AUTHORITIES SUBMITTED PURSUANT TO THE
COURT ORDER OF NOVEMBER 16, 1977**

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UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Civil Action No. 76-1308

PETER H. FORSHAM, *et al.*, Appellants

v.

JOSEPH A. CALIFANO, JR., *et al.*, AppelleesSUPPLEMENTAL MEMORANDUM OF POINTS AND
AUTHORITIES SUBMITTED PURSUANT TO THE COURT ORDER
OF NOVEMBER 16, 1977

INTRODUCTION

This supplemental memorandum is filed in response to the Order of this Court of November 16, 1977. The parties in *Forsham, et al. v. Califano, et al.* were directed to address the following questions:

(1) What impact, if any, does the order of Secretary Califano of July 25, 1977 suspending new drug applications of Phenformin and the subsequent hearings have on the status of this case?

(2)(a) Have the raw data of the UGDP study been made available to appellants, or is it likely that these data will be made available to appellants in the foreseeable future, either in connection with the pending post-suspension proceedings on Phenformin or otherwise?

(2)(b) If so, will that moot the case?

(3) Should this Court remand the case to the district court for further findings in connection with either question (1) or (2)?

SUMMARY STATEMENT OF FACTS

Appellants, in this Freedom of Information Act case, (5 U.S.C. § 552), are distinguished physicians who are specialists in the treatment of diabetic patients. As individuals and as members of the Committee for the Care of the Diabetic (CCD), an unincorporated, non-profit association of physicians and diabetic patients, these appellants have been attempting to gain access to the University Group Diabetes Program (UGDP) study raw data for the purpose of objective review and analysis since 1970, when UGDP results were first published.¹ The objective of these plaintiff physicians was in 1970, and remains today, to open this unprecedented federally-funded study to review by the medical and scientific community in order to insure that government action which relies on the published summaries of the UGDP reflects credible underlying scientific data. Vitally interested in this matter is this nation's community of ten million diabetic patients.

Attempts by plaintiffs to gain access to UGDP raw data began with informal written requests in 1970. However, as the FDA, and later the Secretary of HEW, relied on the study's published results, without even examining the underlying raw data, for a series of administrative actions, appellants were drawn into these individual administrative proceedings to assert the need for an unbiased analysis of the raw data to determine if the actions based on the published results were justified. The description of the administrative actions involving the UGDP study which appellants have placed before the Court² reveals that the pub-

¹ University Group Diabetes Program, The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients With Adult-Onset Diabetes. Part I: Design, Methods and Baseline Characteristics. Part II. Mortality Results; *Diabetes* 19 (Supp. 2): 747-830 (October 1970).

² Brief for the Plaintiffs-Appellants, at pp. 6-10 and Appellants Motion for Further Hearing of September 13, 1977.

lished summaries have precipitated a complete realignment through federal regulation of the treatment of diabetic patients.

Participation by appellant-physicians as individuals or as members of CCD in the challenge of Secretary Califano's imminent hazard suspension of phenformin hydrochloride (hereinafter phenformin)³ and as participants in the FDA withdrawal hearings which ensued from that suspension, has been directed toward this goal of gaining access to the UGDP raw data and thereby placing agency action on a sound basis. Unless public access is thereby gained to all of the UGDP raw data, resolution of the present actions involving phenformin cannot be effected. Nor is the urgent need for the review of the raw data to which this Freedom of Information Act case is directed diminished since other Agency actions are proposed in reliance on the published results of the UGDP. Rather, the legal and scientific case for its production by order of this Court has been strengthened by the fact that the FDA is relying upon the UGDP in the phenformin proceedings.

RESPONSES TO COURT OF APPEALS' INQUIRIES

Set out below are specific responses to the inquiries of the Court:

(1) *What impact, if any does the order of Secretary Califano of July 25, 1977 suspending new drug applications of Phenformin and the subsequent hearings have on the status of this case?*

The impact of the phenformin suspension and the resulting withdrawal hearing is to increase the urgency of appellants' claim. Secretary Califano relied on the UGDP study as the only controlled experiment which supported his ac-

³ *Forsham et al. v. Califano*, No. 77-1408 (D.D.C., filed Sept., 1977).

tion.⁴ FDA witnesses at the administrative withdrawal hearing described the UGDP study as the best evidence available on the issues before that administrative tribunal.⁵ At the administrative hearing, Administrative Law Judge Daniel J. Davidson recognized the importance of the production of the underlying data, however, he felt powerless to require its production due to his lack of subpoena power.⁶ He also ruled that he could not wait for the determination of this Court regarding availability of the data due to the expedited nature of the hearing following the imminent hazard suspension.⁷ Administrative Law Judge Davidson reluctantly concluded that the hearing must proceed despite a failure to gain access to the raw data, concluding that the UGDP reference may have to be stricken or given no weight as evidence to support the FDA's withdrawal of phenformin.⁸ Additionally, as shown in Appellant's Motion for Further Hearing, the UGDP results have been impeached based on even the available information.⁹

⁴ Order of the Secretary of Health, Education, and Welfare Suspending Approval of the New Drug Applications for Phenformin of July 25, 1977 at p. 38.

⁵ Transcript of Phenformin Administrative Hearing (hereinafter Transcript) at p. 341; Phenformin Administrative Hearing Exhibit B-481, at p. 8.

⁶ Transcript of Pre-hearing proceedings of October 4, 1977 at pp. 18, 19.

⁷ Transcript at p. 137.

⁸ Transcript at pp. 153-156.

⁹ See Appendix E of Appellant's Motion for Further Hearing of September 13, 1977. As Appendix C to this memorandum of December 5th, appellants have additionally submitted for the attention of this Court the brief with accompanying appendices which CCD filed at the phenformin administrative hearing. This material is not submitted for the purposes of fact-finding by the Court, rather it is illustrative of the thorough impeachment of the UGDP study's results and the potential value of the raw data to an informed judgement on phenformin and other matters of importance to the diabetic patient.

These undisputed facts from the phenformin hearings, show the recognized importance of the UGDP underlying data on the merits of phenformin withdrawal. The actual impact of these legal proceedings is on the over 300,000 diabetic patients who, after consultation with their physicians, were receiving phenformin therapy. Their supply of phenformin was cut off on October 23, 1977. These patients continue to be irreparably harmed by decisions made which greatly affect them but are made without the benefit of public access to the raw data of the UGDP study, "the best evidence" available concerning phenformin use. For these patients, an ultimate Court reversal of the administrative withdrawal of the drug after it has been unavailable for many months or years cannot reverse the effect done to their course of therapy. A decision by this Court to require that the public have access to UGDP raw data is still in time to provide the administrative tribunal with evidence that all parties have conceded is crucial to a decision on the issues before it.

As appellees have noted in their response to Appellants' Motion for Further Hearing of September 13, 1977, the usefulness in pending litigation of information sought in a Freedom of Information action to the party seeking disclosure has not been considered a determinative factor. See *Sterling Drug v. F.T.C.*, 450 F.2d 698, 704-705 (D.C. Cir. 1971). And equitable principles generally have not been accepted as a rationale for *denying* requests for production under the Freedom of Information Act. *Bannercraft Clothing Company v. Renegotiation Board*, 466 F.2d 345, 353-354 (D.C. Cir. 1972).

However, to effectuate the Congressional policy reflected in the Act, which is to facilitate rather than limit production of information, *Department of Air Force v. Rose*, 405 U.S. 352, 360 (1976), courts have recognized that the public good resulting from disclosure must be weighed. "The effect on the public is the primary consideration." *G.S.A. v.*

Benson, 415 F.2d 878,880 (9th Cir. 1969). See also, *Getman v. N.L.R.B.*, 450 F.2d 670,678 n.25 (D.C. Cir. 1971) and *Theriault v. U.S.*, 503 F.2d 390, 392 (9th Cir. 1974). The beneficial effects of public access to the UGDP data will accrue to the millions of diabetic patients through a more informed decision by the District Court in *Forsham, et al. v. Califano*, Civil Action 77-1478, and in the decision of the Administrative Law Judge in the phenformin administrative hearing. In fact, the future course of all medical therapy for the diabetic patient would be aided, since the scope of the UGDP study is equally that broad.

2(a) *Have the raw data of the UGDP study been made available to appellants, or is it likely that these data will be made available to appellants in the foreseeable future, either in connection with the pending post-suspension proceedings on phenformin or otherwise?*

No raw data has been made available to appellants or any other members of the public. There has been no change in the government position over the last seven years, which is to shield the underlying data from critical review and, therefore, no likelihood that appellants or other members of the scientific community will gain access to the raw data unless this Court orders its production. The technical defense of the FDA evidently continues to be the location of this data outside the confines of a government office building.

On the insistence of the Administrative Law Judge, some UGDP information (*not* the raw data) of which the FDA had possession was distributed to the participants at the phenformin administrative hearing.¹⁰ This information was

¹⁰ The Administrative Law Judge, Daniel J. Davidson, ruled that he could not order production of the raw data due to his limited authority under FDA regulations. See Appendix A for this Order concerning production of UGDP raw data.

gathered by an FDA audit of the UGDP study data. (See Appendix B for the protocol of this audit.) It was from this second-hand collection of some of the data from a few of the patients studied which provided the materials for the testimony at the administrative hearing impeaching the UGDP study's credibility. (See Appellants' Additional Allegations to Appellants' Motion for Further Hearing of September 13, 1977.)¹⁴

The audit materials were the result of a limited review of UGDP raw data by personnel from the FDA's Baltimore office.¹¹ Selected information was taken from the raw data and recorded on special audit forms.¹² Computer retrieval was utilized.¹³ During this process, the FDA was reportedly careful not to bring raw data into its office buildings and thereby compromise its legal theory. The bulk of the raw data of this federally-funded study has still not been reviewed by FDA personnel. It should be observed that the process which was employed by the auditors did not disrupt the data center in Maryland. In fact, the data is evidently stored for the purpose of easy retrieval. Further, personnel from a small district office were assigned the task rather than a deployment of large numbers of personnel.¹⁵ Government objections to the practicality of reasonable public access to this data are thereby rebutted.

2(b) *If so, will that moot the case?*

Only the full and complete public access to UGDP raw data for the purpose of objective scientific review would moot the present action of appellants. Actions by the gov-

¹¹ Appendix B, at p. 1.

¹² *Id.*

¹³ See Appendix B, at p. 1.

¹⁴ See Appendix C.

¹⁵ See Appendix A, at p. 1.

ernment over the last seven years make it clear that only through judicial order will such public access be gained. This case is not moot and there is no likelihood that it will become so in the foreseeable future.

(3) Should this Court remand the case to the district court for further findings in connection with either question (1) or (2)?

Further factual determinations are not required for the Court to rule on the merits of this Freedom of Information Act case. Essential facts placed before this Court relating to the phenformin proceedings are all matters of public record and not subject to dispute. Rather than indicate a need for a remand, appellants believe that these facts underline the importance of a re-evaluation of the District Court's legal conclusions by this Court.

The phenformin Administrative proceedings have answered the question which was asked on oral argument by the Court regarding the existence of adequate alternative remedies for the production of the data. Even second hand audit information possessed by the FDA was not given to appellants, as was promised by the attorney for federal appellees at the oral argument. Only when the Administrative Law Judge required such production was this information received by appellants. Since the oral argument before this Court, the FDA has placed primary reliance on the UGDP at the phenformin administrative hearing and for the drug's imminent hazard suspension and completed its audit of the raw data. Despite these facts that further diminish the plausibility of the FDA's major legal defense that the UGDP raw data is not an agency record, the FDA continues to withhold the data.

This intransigence violates a principle which the FDA has recognized as valid in its own regulations. If the FDA had funded the UGDP study rather than its sister HEW agency, the National Institutes of Health, 21 C.F.R. Sec.

20.109 would dictate its production. This regulation, which was issued on March 22, 1977, requires that all data obtained by FDA contract be made available for public disclosure. However, this Court need not make a ruling as broad as this FDA regulation to order public access to the UGDP underlying data. Appellants continue to assert that the following factors dictate public access to the UGDP raw data:

- it is a 100 percent federally-funded, multi-million dollar study funded by taxpayers.
- the study is the product of government coordination of 12 study centers through central planning and data storage and represents a federal government participation in research which differentiates the UGDP from the many health research and other private activities which receive federal funding.
- the scale of the UGDP study, the time required for its completion and the resources made available to it through federal funding make the study non-replacable by private efforts and a unique public resource.
- by contract and through regulation, the raw data from this study is available for government review, copying and storage in government facilities.
- the FDA has utilized its rights under contract and regulation to access to the raw data and demonstrated its complete dominion and control over this raw data through the recent audit process.
- the published reports of the UGDP study have been relied on for many administrative actions affecting a broad segment of the public.
- based on available information, the study's results have been impeached and the public's need for an unbiased review of the raw data demonstrated.

- access to the data is sought by responsible, expert professionals qualified in the area of the study who can properly utilize the opportunity of access to the raw data for the benefit of the medical community, their patients and the Federal Government.

CONCLUSION

Wherefore, appellants move for an expedited determination by this Court entering judgment for appellants and reversing the judgment of the District Court.

Respectfully submitted,

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Dated: December 5, 1977

Notice: This opinion is subject to formal revision before publication in the Federal Reporter or U.S. App. D.C. Reports. Users are requested to notify the Clerk of any formal errors in order that corrections may be made before the bound volumes go to press.

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., APPELLANTS

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of
Health, Education and Welfare, et al.

Appeal from the United States District Court
for the District of Columbia
(D.C. Civil 75-1608)

Argued December 2, 1976

Decided July 11, 1978

Harvey W. Freishtat, with whom *Anthony J. Rocco-grandì* was on the brief, for appellants.

Michael Kimmel, Attorney, Department of Justice, with whom *Rex E. Lee*, Assistant Attorney General, *Earl J.*

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Silbert, United States Attorney and *Leonard Schaitman*, Attorney, Department of Justice, were on the brief, for Federal appellees.

Mary Elizabeth Kurz, Assistant Attorney General of the State of Maryland, with whom *David H. Feldman*, Assistant Attorney General of the State of Maryland was on the brief, for appellee, *Klimt*.

Before: *BAZELON*, *LEVENTHAL* and *MACKINNON*, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge LEVENTHAL*.

Concurring opinion filed by *Circuit Judge MACKINNON*.

Dissenting opinion filed by *Circuit Judge BAZELON*.

LEVENTHAL, Circuit Judge: In its broad aspect this appeal presents the question whether and under what conditions data compiled by a private group that is receiving money under a federal grant-in-aid program are or become "agency records" by virtue of the fact that the agency has funded the program and has the authority to demand those records.

An action was brought by specialists in the treatment of diabetes, as individuals and a committee,¹ to obtain raw research data of the University Group Diabetes Program (UGDP). The program is a privately conducted and federally funded long-term clinical study of the treatment of diabetes, that has reported certain harmful consequences attendant upon the long-term use of oral hypoglycemic agents. Plaintiffs question the validity of the study, and are concerned lest a useful therapeutic tool be unnecessarily removed from the market. They

¹ Three physicians sue in their own behalf, and in behalf of the Committee on the Care of the Diabetic, described in the complaint as an unincorporated association of 178 physicians involved in the daily treatment and management of diabetes.

seek access to the raw data in order to implement their challenge to the study's validity.

The action was brought under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. That Act is addressed to each "agency" of the Federal Government as defined.² Broadly speaking, and subject to exceptions, it directs each agency to make available to the public certain information, and also "agency records." It establishes the District Court's "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B).

A. BACKGROUND

1. *The UGDP Study and the Sponsoring Institute*

The UGDP is a study funded by 13 federal grants administered by the National Institute of Arthritis, Metabolism and Digestive Diseases (hereafter sometimes Institute or NIAMDD). That institute is an "agency" under the Act, being part of the National Institutes of Health, which in turn is an organization within the Public Health Service, in the Department of Health, Education and Welfare. The grants were made under the statutory grant-in-aid authority of the Public Health Service Act, 42 U.S.C. § 241(c). The grants were made to each of 12 participating university medical centers on the basis of their applications, and a grant was made

² 5 U.S.C. § 552(e):

For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

to the UGDP Coordinating Center at the University of Maryland.³

The pertinent background facts are presented in the affidavit of Dr. G. Donald Whedon, Director of NIAMDD:

4. The inspiration for the UGDP study came from private non-government physicians and scientists in mid-1959. Between 1959 and 1961, before the study actually began with the entry of the first patients, the design, methods, and objectives of the study were evaluated by persons associated with the UGDP and representatives of NIAMDD. The Food and Drug Administration was not involved in the planning, in-

³ The institutional grantees are:

Case-Western Reserve University
Cincinnati, Ohio
Greater Baltimore Medical Center
Towson, Maryland
Jewish Hospital and Medical Center of Brooklyn
Brooklyn, New York
Virginia Mason Research Center
Seattle, Washington
Massachusetts General Hospital
Boston, Massachusetts
Rush-Presbyterian-St. Luke's Medical Center
Chicago, Illinois
University of Alabama
Birmingham, Alabama
University of Cincinnati
Cincinnati, Ohio
University of Maryland
Baltimore, Maryland
University of Minnesota
Minneapolis, Minnesota
University of Puerto Rico
San Juan, Puerto Rico
Washington University of St. Louis
St. Louis, Missouri
West Virginia University
Morgantown, West Virginia

ception, or design of the UGDP study. The study was funded by NIAMDD as part of its responsibility to support research in the field of diabetes and not with any specific regulatory objective in mind.

* * * * *

9. The UGDP raw data (e.g., patient charts and forms) are the property of the individual investigators and the Coordinating Center and are not owned by NIAMDD. Furthermore, it is not the normal practice of NIH or this Institute to require grantees to submit their raw data for review and, in fact, submission of raw data to the institute is extremely rare. Management of the day-to-day operations of grant-supported activities is the responsibility of the grantee. Supervision of the grantee's funded activities by this Institute is generally limited to review of periodic reports submitted by the grantee. (45 CFR §§ 74.80, 74.82). Due to the large number of research grants outstanding—currently approximately 1800—it would not be physically possible for the Institute to subject raw data, if submitted, to critical review, and to require submission of the raw data of the UGDP study would have been an extraordinary requirement. It is the practice to evaluate applications for renewal grants on the basis of progress reports and final reports submitted to NIH. This practice was followed with respect to the UGDP grants. No specific provisions of the UGDP grants required submission of raw data to the Department of Health, Education and Welfare. Pursuant to 45 CFR § 74.23, officers or employees of the Department could obtain access to the raw data for purposes of audit inspection and copying if access is deemed pertinent to the grant. The raw data which are the subject of this case have never been seen by, or been in the possession of, any officer or employee of the National Institutes of Health. * * *

The particular documents sought by the plaintiffs in this case are observations on over 1000 diabetic patients,

who were monitored from 5 to 8 years. It is estimated that there are some 55 million such documents.

In June, 1970, the UGDP investigators made a presentation of the methods and initial results of their study at the annual meeting of the American Diabetes Association. The results indicated that the administration of tolbutamide (an oral hypoglycemic drug) to mild adult-onset diabetics led to a death rate from cardiovascular disease higher than that of groups treated with diet alone, with a fixed dosage of insulin, or with a variable dosage of insulin. The findings were published in the December 1970 Journal of the American Diabetes Association. During 1970 and 1971, over a dozen articles were published in medical journals concerning the study, some supportive and some critical.⁴

The NIAMDD contracted in 1972 with the Biometric Society, a private international professional society of biostatisticians, for an in-depth assessment of the quality of the UGDP study. The Society made a report to the Institute in 1974 that apparently found some merit on both sides of the controversy. It concluded that while some of the criticisms of the UGDP study were valid most were unpersuasive, and the evidence of harmfulness adduced in the UGDP study was "moderately strong." This was made public in the American Medical Association Journal for February 1975.⁵

2. Food and Drug Administration

The Food and Drug Administration of HEW, on being apprised of the UGDP results, issued in its October, 1970, Bulletin to the medical community a recommendation that tolbutamide should be used only in cases of adult-onset,

⁴ For a listing see 40 Fed. Reg. at 28592.

⁵ 131 AMAJ 615.

stable diabetes that could not be controlled by diet and could not be treated with insulin. A June, 1971, FDA bulletin proposed changes in labeling of oral hypoglycemic drugs to warn of cardiovascular hazards. Plaintiff committee sued to enjoin the proposed labeling on ground of deficiencies in the UGDP study, and the First Circuit remanded to the FDA for exhaustion of administrative remedies.⁶

The FDA deferred further action on the labeling pending the review of the UGDP study by the Biometric Society. As already noted, the 1974 report of the Biometric Society was mixed, but overall found "moderately strong" evidence of harmfulness in the UGDP study. Its contract with NIAMDD did not require the Society to seek access to the UGDP raw data, but it apparently did examine some of the raw data.⁷ The contract did not require the Society to submit any raw data to the Institute, and none was submitted.

⁶ *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973). Plaintiffs contended *inter alia* that prior to regulatory action, the UGDP raw data should be made available to the scientific community. In reversing a preliminary injunction restraining the proposed relabeling, the First Circuit remanded to the FDA, ruling that the underlying questions required review on the full administrative record. Judge Coffin's opinion takes note (p. 414, fn.4) of plaintiffs' contention that the record must include, *inter alia*, the original patient records of the UGDP study, and continues: "While in light of our discussion we need not resolve the propriety of each of these requests, we reiterate what we recently said in an analogous situation: 'We think the law requires production of the entire administrative record . . . where the correctness of factual findings are [sic] involved. . . .'"

⁷ Plaintiffs say this access was impaired by Society-imposed limitations: to data for only one of the hypoglycemics studied, and only the period prior to October 1969.

3. FOIA requests and District Court proceedings

Stressing that the raw data had been made available to the Biometric Society, plaintiffs' committee began a series of FOIA requests in 1974 and 1975 for access to the raw data and a copy of the draft report of the Biometric Society. Plaintiffs were given preliminary galley proofs of the report later published in the AMAJ. HEW notified plaintiffs on August 7, 1975, that the raw data were the property of those engaged in the UGDP study and had not been reviewed or even seen by either the UGDP sponsor (NIAMDD) or FDA.

This FOIA action was begun on September 30, 1975. The complaint sought the production of the raw data, defined as consisting of the forms transmitted to the Coordinating Center and the computer tapes and/or programs on the basis of which the data were analyzed. The complaint also sought a draft report of the Biometric Society.*

On Feb. 5, 1976, the district court granted the motion of the HEW officials to dismiss the complaint, on the ground that no official or employee of HEW is now or has ever been in possession of the raw data relating to UGDP, that these raw data are the property of the individual investigators and UGDP study coordinating center, and in the Center's possession, custody and control; that neither the investigators nor the Coordinating Center is an "agency" within 5 U.S.C. § 552, and that the raw data are not "agency records" subject to the disclosure provisions of FOIA.⁹

* It is not clear what draft report is intended, other than the galley proofs already supplied of the subsequently published in February, 1975, see fn.5, above.

⁹ The district court dismissed as moot a motion by defendant Dr. Klimt, the director of the UGDP Coordinating Center at the University of Maryland, to quash service of process. Dr.

4. Developments pending appeal

On July 25, 1977, while the appeal to this court was pending, Secretary of HEW Califano issued an imminent hazard order suspending new drug applications for phenformin (another oral hypoglycemic drug), and there ensued administrative withdrawal hearings. This court requested supplemental memoranda of the parties on the question of whether data that would become available to plaintiffs as a result of these administrative proceedings would moot the present controversy. The federal appellees put it that there is neither certainty nor likelihood that plaintiffs will obtain access to all the data they seek as a result of the phenformin proceeding. They note, for one thing, that phenformin was only one of the oral hypoglycemic drugs subject to the warning of the UGDP study, the principal one being tolbutamide.

However, it appears that the FDA did examine certain of the underlying raw data (a small portion, quantitatively) in the course of a recent limited audit of the UGDP, and that this portion of the underlying information (except patient-identifying information) has been made available to plaintiff-appellants, and to other interested persons, participating in the phenformin proceeding. The federal appellees' memorandum states: "The FDA has no present intention of obtaining the remaining portions of the UGDP raw data through the auditing rights of the Secretary."

B. ANALYSIS

We rule that the public at large does not have a right under the Freedom of Information Act to the underlying

Klimt's directorship was based on his position as Director of Clinical Investigation in its School of Medicine. He was represented by the office of the Attorney General of Maryland.

raw data in the hands of the investigators and university groups who conducted the UGDP study program of diabetes under grants from the federal government.

1. The plaintiffs are a respected group of medical specialists asserting that their access to the data would inure to the public interest, by virtue of their concern that the use of drugs they deem valuable may be inhibited. We begin our analysis by observing that in this proceeding under the Freedom of Information Act, the court cannot give any weight to such a consideration.

The only claim ascertainable in this FOIA action is the right of any member of the public, motivated by whatever reasons. The Freedom of Information Act does not depend on a showing of need or interest by the particular applicant for the records. Any showing of need or interest is irrelevant.¹⁰ Such considerations as need, interest, or public interest may bear on the agency's determination of the order of processing applications, but they have no bearing on the substantive right under FOIA to access to the document.¹¹

¹⁰ *Sterling Drug, Inc. v. FTC*, 146 U.S.App.D.C. 237, 244, 450 F.2d 698, 705; *Robles v. EPA*, 484 F.2d 843, 847 (1973), repeating the quotation from *K. Davis, Administrative Law*, 1970 Supp. § 3A.22 (disclosure was never to "depend upon the interest or lack of interest of the party seeking disclosure").

See also *K. Davis, id.* at § 3A.29: "The Act never takes into account the need of the party seeking the disclosure; it never calls for balancing that need against the interest of a party adversely affected by disclosure. This policy choice reflects pressure from the press that 'the public as a whole has a right to know.'"

¹¹ It is not relevant under FOIA that the published results of the UGDP were controversial; or that, as plaintiffs allege, the government relied on these results. If the Government examined "UGDP raw data at first hand" (dissent at 10), such data have become agency records and are subject to FOIA. If the Government has relied on results of a study

2. To avoid any possible misunderstanding, we articulate that our ruling embodies no implication as to whether plaintiff physicians will have a right of access to the data underlying the UGDP study in connection with any existing or future actions of the Food and Drug Administration. That issue is distinctly different from what is before us now, and would have to be decided in the light of the record before the FDA.¹²

based on data that it has not examined, a challenge that this was arbitrary—a matter we do not here decide—may proceed by well-established mechanisms independent of FOIA.

¹² Plaintiffs' memorandum puts it that the First Circuit's opinion impliedly recognizes such a right. While a glimmer of sympathy for plaintiffs' position may be extracted from a reference in that opinion, tucked away in a discreet footnote, all that is said by the court is that the case in court must be determined on the basis of the entire administrative record. The issue here is whether the data in the hands of the researchers are part of the agency's records.

The issue of fairness to plaintiffs will require attentive consideration in the light of the administrative record. When issues of risk of harm are involved, an agency may use results of scientific researchers even without access to underlying data, as is evidenced by the frequent use of foreign studies, see *e.g.*, *Ethyl Corp. v. EPA*, 176 U.S.App.D.C. 373, 400, 541 F.2d 1, 28 (en banc), *cert. denied*, 426 U.S. 941 (1976). In the present case the government has undertaken some audit review of the raw data. Plaintiffs' memorandum argues that this audit was subject to limitations that undercut its utility, but obviously we cannot appraise that issue on the record before us at this time. A court reviewing the situation on the entire administrative record would also take into account the appraisal of the Biometric Society. We cannot on our record appraise its work and its significance, let alone either plaintiffs' aspersions on the way in which that Society's committee conducted itself or the government comment that its membership embraced a wide span of scientific opinion.

The Biometric Society set forth flaws in the work of the UGDP investigators, but when an investigation requires a protracted period flaws are not wholly unexpected, and their

The FDA and NIAMDD are both in HEW, but that department is a conglomerate that embraces many and distinctly different activities. Insofar as it is engaged, through FDA, in a regulatory program, it may be subject to requirements of revelation that go beyond the FOIA's rules that govern all agencies. The FDA's regulatory actions are not before us in this FOIA lawsuit, which focuses on whether data become HEW records by virtue of study and granting activities (of NIAMDD).

3. This action requires that the persons invoking the FOIA show that they seek "agency records." The NIAMDD is a government agency, of course. But the persons or institutions who receive study grants from that Institute, or indeed from any branch of the federal government, do not on that account become government agencies.

To some extent, our path is lighted by *United States v. Orleans*, 425 U.S. 807 (1976). The case involved the Warren-Trumble council, a community action agency operating as a non-profit corporation under Ohio law, that was funded entirely by a federal agency, the Office of Economic Opportunity. Under the Economic Opportunity Act of 1964, the OEO furnished financial assistance to a community action agency, in turn defined as one designated by the state to plan and administer a community action program of "services and activities having a measurable and potentially major impact on causes of poverty in the community." The issue was whether or not one of the activities of the Ohio community action agency, the sponsoring of recreational out-

appearance may still leave the study with utility for appraisal of risk of harm to the public. See *Certified Color Manufacturers Assoc. v. Mathews*, 177 U.S.App.D.C. 137, 543 F.2d 284 (1976). The reviewing court would also consider the reasons, if any, given in any FDA proceeding involving oral hypoglycemic drugs for denying participants access to the raw data.

ings for children, if conducted negligently, could give rise to an action under the Federal Tort Claims Act. The Supreme Court held that it could not, since the council was not a federal agency or instrumentality, and its employees not federal employees. The Court found that a critical element in distinguishing a federal "agency" from either a contractor with the federal government or a grantee of the federal government, was the federal government's "control [of] the detailed physical performance." ¹³

Our decision today is congruent with our decision in *Washington Research Project v. HEW*, 164 U.S.App.D.C. 169, 504 F.2d 238 (1974), which reversed a district court order granting disclosure of certain reports made to the National Institute of Mental Health, a unit of the Public Health Service of HEW. The case involved reports made, on applications for research support, by peer review groups ("initial review groups" or IRG). The IRG peer review system was established by the government to assure competent evaluation of proposals through the use of "expertise of nongovernmental consultants functioning in panels organized around particular specialized disciplines within the broader field of biomedicine." ¹⁴

¹³ At fn. 5, 425 U.S. at 816, the Court put it that the issue was whether "there was day to day control of a program," it being irrelevant whether the program was funded by means of a contract or grant. The Court stressed (425 U.S. at 815): "Billions of dollars of federal money are spent each year on projects formed by people and institutions . . . responsible to the United States for compliance with the specifications of a contract or grant, but they are largely free to select the means of its implementation." The Court found it irrelevant that the local council did not obtain funds from any other sources or conduct any programs without federal money (425 U.S. at 818 n.7).

¹⁴ 504 F.2d at 242.

The reports sought included a "site visit" to observe the pertinent experimental technique, and a "summary statement" of the observations and deliberations of the group, prepared by a NIMH staff member assigned to assist the group. The legal issue focused on whether the initial review group was itself a government "agency," in which case its own reports would be "final opinions" required to be disclosed under FOIA, and not intra-agency memoranda excluded under exemption 5. Acknowledging the "myriad organizational arrangements for getting the business of the government done,"¹⁵ the court concluded that "the IRG's are advisory committees, performing staff functions through the medium of outside consultancy, and are not agencies."¹⁶ It observed, significantly, "Employing consultants to improve the quality of the work that is done cannot elevate the consultants to the status of the agency for which they work unless they become the functional equivalent of the agency, making its decisions for it."¹⁷

4. Plaintiffs seek to avoid a head-on contention that federal grantees be assimilated as federal agencies. Instead they emphasize a congeries of considerations that they think cumulate to a right of public access to documents in the hands of the grantees.

¹⁵ 504 F.2d at 246.

¹⁶ 504 F.2d at 246.

¹⁷ 504 F.2d at 248. Such consultants are employed and paid under the Public Health Service Act, 42 U.S.C. §§ 210, 217a. The court acknowledged that the consultant group's recommendations were undoubtedly "an often crucial element" in the approval process of the government, which was often typically a "perfunctory review." It regarded the degree of scrutiny as irrelevant to the court's consideration, stating that the fact that the government "may be greatly influenced by the IRG's expert view does not make the IRG an agency."

In addition to the responsibility of plaintiffs and a claim of public interest in their access, which we have already shown to be irrelevant, plaintiffs stress the following: This was a multi-million dollar study, entirely funded by the federal government, of such a scale as to be non-replicable by private efforts and a unique public resource. By contract and regulation, the raw data underlying the study are available for government review, copying and storage. The government's exercise of its rights of audit demonstrates its "complete dominion and control" over the data through the audit process.

The Institute's grant documents establish its right of access to "any books, documents, papers, and records of the grantees" for certain purposes. To the extent that the language of the grant is material, it indicates that these are not agency records prior to the exercise of that right.

Plaintiffs' claim is in effect an assertion that the federal government should be required—formally or constructively—to exercise its contract-grant right of access in order to provide general public access. We cannot accept this proposition. The Freedom of Information Act only gives a right of access to agency records in existence. It does not confer a right to have the government generate agency records, either by creation, subpoena or contract demand. That conclusion is implicit in *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975). The Court there granted the public a right to the production of the agency's appeal memorandum, pursuant to its understanding that the Act "represents a strong congressional aversion to 'secret [agency] law.'" (421 U.S. at 153). However the Court held that the public had no right to a judicial requirement that the agency produce or create explanatory material in the case of an appeals memorandum that referred only conclusorily to the "circumstances of the case." See 421 U.S. at 161:

The Act does not compel agencies to write opinions in cases in which they would not otherwise be required to do so. It only requires disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

The governing principle is that only if a federal agency has created or obtained a record (or has a duty to obtain the record)¹⁸ in the course of doing its work, is there an agency record that can be demanded under FOIA.¹⁹

¹⁸ Judge MacKinnon's opinion leads me to acknowledge that this parenthetical reference is, strictly speaking, dictum. Yet in rejecting the claim that there is an FOIA entitlement because of the *power* of the agency to obtain a record, it seems material to observe that I see a distinction where the agency has the *duty* to obtain the record. In that instance, I do not conceive that the official may lawfully resist the claim for the document on the ground that he has chosen to violate his official duty (to obtain it). In legal terms, the claim and lawsuit are in effect a joinder of two requests, and a joinder of an action in mandamus with one under the Freedom of Information Act.

¹⁹ We do not suggest that mere physical possession of records by a government agency is the sole criterion for determining whether they fall within the scope of FOIA. Obviously a government agency cannot circumvent FOIA by transferring physical possession of its records to a warehouse or like bailee.

Where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program, or whether, by contrast, the entity retains its private character in bona fide fashion during the course of the endeavor that results in the records. Even in the latter situation, however, records that are examined by the government through audit rights may become agency records under FOIA—if, for example, the records are copied by the agency or come into its possession.

5. Overarching policy considerations are stressed by physician applicants. There is a plea for liberal reading of reform legislation. We agree that this reform legislation should not be niggardly construed in contravention of legislative objective. The "basic thrust" of the Act embraces "a general philosophy of full agency disclosure" subject to specific exemptions and the objective "to pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny."²⁰

However, the general policy of avoiding agency secrecy does not give a charter for extending the law beyond the domain of "agency" and "agency records" that is the keystone of the Act. To stretch for data in the possession of federal grantees, cannot be justified as within the fair contemplation of Congress either at the time the law was passed or amended, or even today under a doctrine of trying to reconstruct specific legislative intent in the light of the broad purposes disclosed by Congress.²¹

It is tautology to say that requiring disclosure of grantee records will promote the disclosure policies of FOIA. But disclosure is not required by the statute unless those records are agency records. Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all countervailing considerations.

If the statute is to be given the kind of interpretation sought by plaintiff physicians, the impact would be

²⁰ Department of Air Force v. Rose, 425 U.S. 352, 360 (1976). Opinions of this court to the same effect include Bristol Myers Co. v. FTC, 138 U.S.App.D.C. 22, 25, 424 F.2d 935, 938 (1970); Getman v. NLRB, 146 U.S.App.D.C. 209, 211, 450 F.2d 670, 672 (1971).

²¹ Montana Power Co. v. FPC, 144 U.S.App.D.C. 263, 445 F.2d 739 (1970), *cert. denied*, 400 U.S. 1013 (1971).

far-reaching. The number of documents in any one study would be stupendous—reaching millions in the single case before us. The number of federal grants and contracts is not a matter of record, but as was noted in *Orleans*, they account annually for disbursements in the billions. The awesome implications of plaintiffs' contention cannot be shrugged off because modern technology permits access to documents on tape through computer printouts, without need for physical production.

Scientists engaged in research on federal grants must accept the fact that any documents filed with the federal government, whether on the scientists' own initiative or an audit or other lawful demand, are subject to FOIA. Even in scientific terms, any such audit provides a surrogate for the kind of reliability usually accorded to scientific studies by replication of experiments when feasible. However, an undertaking to be audited by responsible personnel is not the same as an agreement to accept rummaging by the world at large.

The court will not trim FOIA by speculation as to adverse motivation or reaction of the scientists.²² Similarly, the court cannot supply the extension of the reach of the Act sought by plaintiffs by building on a policy speculation that such an extension would not throttle scientific cooperation and research. This involves matters beyond our proper sphere of judicial notice.

What is requested in this action, in our view, is an extension of the statute on claim of public interest that

²² In considering Exemption 4 for trade secrets or commercial information, the court found it irrelevant to inquire whether non-commercial scientists are either "a mean-spirited lot who pursue self-interest as ruthlessly as the Barbary pirates did in their own chosen field," or are governed by the loftier consideration that "secrecy is antithetical to the philosophical values of science." *Washington Research Proj., Inc. v. HEW*, 164 U.S.App.D.C. 169, 175, 504 F.2d 238, 244 (1974).

must be appraised by the legislature which can give the subject extended study, elicit opinions from all interested sources, and consider the pro's and con's.

6. It is fitting to close by referring to the need, in any pondering of such extension of the FOIA, for considering the impact on the philosophy and purpose of Federal grant programs.

Grant programs represent a means for the governance of our society which is rooted in a pluralistic conception of the value of drawing on both private and governmental sources. A leading student of Federal grant law puts it²³

The grant is assistance to an autonomous grantee. The grantee is not an arm, agent or instrumentality of the grantor. The employees of the grantee are not federal employees. The torts of the grantee are not federal torts. The property of the grantee is not federal property.

The reference to "an *autonomous* grantee" is a core concept, not an incidental observation. In a grant program the federal government gets the advantage of services rendered by someone who is doing his own thing, his own autonomous thing. It is not the same as a government operation in disguise.

Through its grants to university groups, the government obtains the efforts of creative persons who flourish in an academic atmosphere. Such arrangements provide a measure of detachment and independence from the mission of the government agency. The researchers may feel the tug of government purse strings, but they also feel answerable to the standards of their academic colleagues.

Plaintiffs cite the multi-million dollar nature of the study as a reason for access. There is at least a ques-

²³ M.S. Mason, *Current Trends in Federal Grant Law-Fiscal Year 1976*, 35 FED BAR 163, 167-68 (1976).

tion whether the federal government could have conducted directly, through its own employees and resources, a study program so long in time, so broad in space, and covering so many patients and controls. Even in a case where the grant is to conduct a study that might conceivably be conducted by federal employees, there is an advantage in terms of effective government and advancement of the public interest if the study is done by various institutions. The government goes beyond the capabilities of its own employees, adding the spirit and insights of the scientists and students who have selected a different life style, at a center of learning.

As earlier noted, we are not concerned here with the kind of case where the federal government exercises detailed control over operations. Such a condition presents different considerations, as noted in *Orleans*. Nor do we have a suggestion of subterfuge, with a federal agency seeking to conduct research outside the scrutiny of government laws, by using facilities that are independent only nominally. The case before us concerns a UGDP study conceived in 1959 by private, non-government physicians and scientists. They developed their own methodology; it was not dictated by the federal government.

Of course, in any program funded by the federal government there is an opportunity for the government to assess the results of the performance and of any studies. There may also be directions by the federal government in certain matters of public policy that are essentially peripheral to the core of the work done. There may, for example, be a requirement of avoidance of discrimination on grounds of race, religion, creed or sex. There may be achievement of other government objectives which apply across the board to all activities financed by the federal government.

The central question is whether the government is really involved in the core of the program. At least in a case such as the one before us, where there was no claim of significant government control of day-by-day operation, or detailed involvement in the planning or execution of the program, the overall concept of autonomy of grantees persists, even though there are federal objectives, right of federal audit and perhaps some over-arching federal requirements.

At least a fleeting reference should be made to acknowledge that some of the federal grantees are institutions of the state governments.²⁴ There are thus considerations of federalism involved. These are not necessarily of constitutional dimension. However, they are not without relevance in appraising the extent to which such grantees are automatically governed by rules provided by Congress for the federal agencies, such as govern access to records and meetings, or personnel management,²⁵ or any other rules.

The foregoing matters indicate that a balance must be struck, one that considers the advantages of grantees that are autonomous and have value because they are not governmental, and the possibly conflicting policy that cherishes full and free public access to government agencies and shuns secrecy as invidious. Such a balancing is a task for the legislature. The extension of access sought by plaintiffs on the ground of public interest is not properly addressed to the courts.

Affirmed.

²⁴ See note 9, *supra*, as to University of Maryland.

²⁵ *National League of Cities v. Usery*, 426 U.S. 833 (1976).

MACKINNON, *Circuit Judge*, concurring: I join generally in Judge Leventhal's opinion but wish to add the following observations.

5 U.S.C. § 552(a) (3) provides: "[E]ach agency, upon any request for *records* . . . shall make the records promptly available to any person." 5 U.S.C. § 552(a) (4) (B) also refers to the location of "*agency records*" as constituting one basis for conferring on the district court for that district "jurisdiction to enjoin the agency from withholding *agency records* and to order the production of any *agency records* improperly withheld from the complaint. In such a case the court . . . may examine the contents of such *agency records* in camera . . ." (Emphasis added.) A fair conclusion from the foregoing indicates that it is not just "records" but "*agency records*" that the statute is addressing.

The court's opinion at page 16 states:

The governing principle is that only if a federal agency has obtained a record (*or has a duty to obtain the record*) in the course of doing its work, is there an agency record that can be demanded under FOIA. [Emphasis added.]

The italicized statement is not necessary to our decision and I do not join in it. Each particular case involving a request for records not in the possession of an agency but for which, it is alleged, there is some duty to obtain the records must be decided on its particular circumstances. I would leave to a future opinion any declaration as to the extent to which FOIA should be interpreted to cover records not created by, obtained by, or otherwise in the possession of an agency. The plain implication derived from the language of the statute is that it does apply to records which belong to the agency or are in its possession—that is, records which the agency has created or obtained. That is all that is needed to decide

this case. I would not refer to records about which it might be said that an agency might have some duty to obtain until such time as we are presented with a case that raises the question directly and presents to us all the relevant facts necessary to decide the applicability of FOIA to that situation.

The dissent would go even further and substitute for the normal interpretation of the language of the statute a meaning to be derived from an extraneous examination of "*all the relevant circumstances surrounding the creation, preservation, and use of [the] particular records*" (Dissent at 6, emphasis original). Then, "[i]f this analysis reveals a significant degree of federal involvement with the records, then they should be considered agency 'records' subject to FOIA" (*Id.*, footnote omitted). The *catch* is allowing the interpretation of the statute to turn upon what a judge might consider a "*significant degree of federal involvement*." The attempt is to impose a "chancellor's foot" standard which varies with each judge. The statute, however, is not susceptible of such construction, and happily so, for those whose foot gives them a short standard would find records to be "*agency records*" wherever there was any federal funding or access to the records. That standard, as applied by some courts, would extend FOIA to practically unlimited lengths in those universities and industries which engage in private research. If Congress desires the Act to be so extended, it can do so by enacting appropriate legislation; but my view coincides with that expressed in Judge Leventhal's opinion, that such an extreme extension of the Act should not be created by judicial fiat.

In reaching this conclusion, I see no harm to the public. Where particular records are the subject of legitimate inquiry, as in the two cases referred to in the dissent, they may be subpoenaed by interested parties.

BAZELON, *Circuit Judge, dissenting*: Plaintiffs seek disclosure of the raw data of a federally-sponsored research project, the University Group Diabetes Program (UGDP). The UGDP data are locked in a bank vault in Maryland in the custody of the UGDP program coordinator. For the majority, this means they are not agency "records" subject to disclosure under the Freedom of Information Act (FOIA). With all due respect, I cannot agree.

In my view, factors other than possession are relevant in determining whether the UGDP data are agency "records." The Federal Government has provided all of the funding for the UGDP; the Government has an unrestricted right of access to the data; and importantly, the Government has extensively relied on the UGDP study and data in regulatory action affecting the treatment of diabetes. I think these factors cumulatively establish a significant degree of federal involvement with the UGDP raw data. Accordingly, I would hold that they are agency "records."

I.

The Freedom of Information Act requires federal agencies to disclose all "records," 5 U.S.C. § 552(a) (3),¹ that

¹ [E]ach agency, upon request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

5 U.S.C. § 552(a) (3) (1974). As originally enacted, this section provided:

[E]ach agency, on request for identifiable records made in accordance with published rules stating the time, place, fees to the extent authorized by statute, and procedure to be followed, shall make the records promptly available to any person.

[Continued]

do not fall within one of nine exemptions. *Id.* § 552(b) (1)-(9). No definition of the term "records" is found in either the Act or the legislative history.² The case law, focusing almost exclusively on the exemptions, sheds little light on this term.³ We are thus left with little

¹ [Continued]

The section was amended in 1974 to make clear that "[a] 'description' of a requested document would be sufficient if it enabled a professional employee of the agency who was familiar with the subject area of the request to locate the record with a reasonable amount of effort." H.R. REP. NO. 876, 93d Cong., 2d Sess. 5-6 (1974).

² The 1967 Attorney General's Memorandum does contain one sentence relevant to the definition of agency records. It says: "Subsection (c) [552(a) (3)] refers, of course, only to records in being and in the possession or control of an agency." R. Clark, Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act (1967) *reprinted in* Freedom of Information Act Source Book, S. REP. NO. 82, 93d Cong., 2d Sess. 222 (1974) (emphasis added). Although the Attorney General's Memorandum is a doubtful guide to congressional intent, see K. DAVIS, ADMINISTRATIVE LAW TREATISE 117 (1970 Supp.), the fact that it refers to two criteria for defining agency "records"—possession or control—suggests a more inclusive approach than that adopted by the majority. I would also argue that the Attorney General's Memorandum is consistent with the result I would reach here, since in my view the Government involvement with the UGDP data amounts to "control."

³ *But see* Goland & Skidmore v. CIA, No. 76-1800 (D.C. Cir., May 23, 1978) (congressional hearing transcript in possession of agency not an agency record); SDC Development Corp. v. Mathews, 542 F.2d 1116 (9th Cir. 1976) (materials in medical reference library not agency records); Cook v. Willingham, 400 F.2d 885 (10th Cir. 1968) (per curiam) (presence report in the hands of prison authority not an agency record); Ciba-Geigy Corp. v. Mathews, 428 F. Supp. 523 (S.D. N.Y. 1977) (UGDP raw data not agency records); Nichols v. United States, 325 F. Supp. 130 (D. Kan. 1971), *aff'd*, 460 F.2d 671 (10th Cir.), *cert. denied*, 409 U.S. 966 (1972) (physical evidence relating to assassination of President Ken-

direct guidance in attempting to elucidate a key provision of the Act.

The majority does not discuss the difficulties involved in defining agency "records." It simply asserts, with little supporting rationale, that the crucial question is whether the documents have been "created" or "obtained" by a federal agency.⁴ In adopting this approach, the majority joins with the federal defendants and the district court in looking to such factors as property rights and possession in defining agency "records."⁵ I have no

nedy not "records"). I exclude cases that turn on the definition of a federal "agency." *E.g.*, *Soucie v. David*, 448 F.2d 1067 (D.C. Cir. 1971).

⁴ Maj. op. at 16. Apparently, the majority would also recognize agency "records" where the Government is involved in the "core planning or execution" of a program, maj. op. at 16 n. 19, 21; and where a federal agency has a duty to obtain records. Maj. op. at 16. *But see* concurring op. at 1.

⁵ The district court found that

(1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institute of Health (NIH), the Food and Drug Administration (FDA), or the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) . . . ; (2) the raw data in question is [sic] the property of the individual investigators and UGDP coordinating center and remains in the possession, custody and control of the UGDP study coordinating center. . . ; (3) neither the individual investigators nor the UGDP study coordinator is an 'agency' within the purview of the Freedom of Information Act, 5 U.S.C. § 552; and (4) consequently, the raw data in issue are not 'agency records' subject to the disclosure provisions of the Freedom of Information Act, 5 U.S.C. § 552(B).

Joint Appendix (J.A.) at 146-47 (footnote omitted).

[Continued]

objection to title or custody as relevant criteria. I do object, however, to a test based on only some of many possibly relevant factors, with little justification offered for the primacy of these factors. The place to start in determining the scope of agency "records" is not with assertion, but with an examination of the policies of the FOIA.

There can be no doubt about the basic goals of the Freedom of Information Act. As the Senate Report put it, the fundamental premise of the Act is that "the public as a whole has a right to know what its Government is doing." S. REP. NO. 813, 89th Cong., 1st Sess. 5 (1965). FOIA was designed, in the words of the Report, "to establish a general policy of full agency disclosure unless information is exempted under clearly delineated statutory language. . . ." *Id.* at 3. In the House, Congressman after Congressman rose to speak in support of the policy underlying the bill. This was, as they variously put it, the right to the public "to information relating to the actions and policies of Federal agencies," 112 CONG. REC. 13655 (1966) (remarks of Rep. Hall); "to know the facts about the operation of their government," *id.* at 13657 (remarks of Rep. Reid); "to be fully informed about the policies and activities of the Federal Government," *id.* at 13648 (remarks of Rep. Faschell). These statements suggest the need for a broad definition of agency "records": broad enough to let the public know everything "its Government is doing;" to illuminate all "policies and activities of the Federal Government."

⁶ [Continued]

The federal defendants' position is that "the term 'agency records' in the Freedom of Information Act applies to 'records' in the possession of a federal agency or owned by an agency, or produced under the day-to-day supervision of an agency." Gov. Br. at 17.

The principle that "the disclosure requirement be construed broadly. . .," *Soucie v. David*, 448 F.2d 1067, 1080 (D.C.Cir. 1971), is also rooted in the structure of FOIA. Before FOIA was enacted, the public information section of the Administrative Procedure Act allowed agencies to withhold information "in the public interest," or "for good cause shown," or if the person seeking the information was not "properly and directly concerned." 5 U.S.C. § 1002 (1964). These broad exemptions created what was in effect a "withholding statute," not a "disclosure statute."⁶ To remedy this situation, Congress enacted a statute containing a general disclosure section and nine narrowly drawn exemptions. The disclosure section provided that "any person" could have access to any agency "record," without having to state a reason for wanting the information. And the exemptions were drafted to provide "definitive guidelines"⁷ as to what information could be withheld. To avoid new loopholes, Congress expressly limited the grounds for nondisclosure to those specified in the exemptions.⁸ The objective was to "make it clear beyond doubt

⁶ S. REP. No. 813, *supra* at 5.

⁷ *Id.* at 3.

⁸ This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section.

5 U.S.C. § 552(c) (1970).

I agree that in enacting FOIA Congress struck a deliberate balance between a policy of full disclosure and various countervailing policies. Maj. op. at 17. But the legislative history makes it abundantly clear that all of the competing policies Congress saw fit to recognize were to be accommodated through nine specific exemptions. It comes as a surprise, therefore, to learn that a policy not mentioned by Congress—that of preserving grantee "autonomy," maj. op. at 19 is to be realized through a restrictive definition of agency "records."

that all *materials of the Government* are to be made available to the public by publication or otherwise unless explicitly allowed to be kept secret by one of the exemptions in [§ 552(b)]." S.REP.No. 813, *supra* at 10 (emphasis added in part).

Both the purpose and the structure of FOIA point to a broadly inclusive definition of agency "records"—a definition encompassing "all materials of the Government." I seriously doubt that common law notions of property or custody can define the totality of such records. In my view, the appropriate approach under the statute is to examine *all* the relevant circumstances surrounding the creation, preservation, and use of particular records. If this analysis reveals a significant degree of federal involvement with the records,⁹ then they should be considered agency "records" subject to FOIA.

II.

Plaintiffs emphasize three forms of federal involvement with the UGDP research data: federal funding of the data, federal access to the data, and federal reliance on the data in administrative decisionmaking. We need not decide whether one of these factors, or even two of these factors in combination, would be sufficient to make the

⁹ Another court that has grappled with whether the UGDP raw data are agency "records" concluded "that the goals and purposes of the Act would be served best by imposing a standard which calls for proof that the records were either Government-owned or subject to substantial Government control or use. In other words, it must appear that there was significant Government involvement with the records themselves in order to deem them agency records." *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523, 529 (S.D. N.Y. 1977). Although I disagree with Judge Tenney's application of this standard, particularly his conclusion that the Government has not directly relied on the UGDP raw data, *id.* at 531, I have no quarrel with his statement of the standard itself.

UGDP data agency "records." Where all three factors are present, however, I think these materials are clearly agency "records."

A. Government Funding

One hundred percent of the UGDP funding was provided by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), one of the institutes of the National Institutes of Health. Federal funding is significant for FOIA purposes for two reasons. First, funding of scientific research is a federal activity, and FOIA was enacted to allow the public to obtain information about all federal activities—including the expenditure of money. As one Congressman put it, FOIA was intended in part to enhance the rights and responsibilities of the voting public by making it possible for them to know "what their Government is doing with their money." 112 CONG.REC. 13659 (1966) (remarks of Rep. Gurney); accord 110 CONG.REC. 17088 (1964) (remarks of Sen. Dirksen).

Federal funding of the UGDP is also important because funding brings with it significant Government control over the use, maintenance, and disposition of the UGDP raw data. This can be seen by examining HEW regulations governing the relationship between the Government and the grant recipient. Under these regulations, the grantee is obliged to retain "financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant" for a period of three years after receiving the grant. 42 C.F.R. § 74.20. If the granting agency determines that any of the records generated by the grantee have "long term retention value," the agency may order the records transferred to the Government for permanent custody. *Id.* § 74.20(b). At all times, the Government has the right of access to "any books, documents, papers, and records of the grantee"

for the purpose of making "audit, examination, excerpts and transcripts." *Id.* § 74.23(a). The regulations further require that the grantee retain all "[l]aboratory notes, related technical data and information" that pertain to a patentable invention, and make them available to HEW upon request. *Id.* § 52.22. And if the grantee copyrights a publication resulting from the grant, the regulations give the Government a royalty free, nonexclusive license "to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so." *Id.* § 52.23. While these provisions probably fall short of establishing full federal ownership of the UGDP data, see Gov. Br. at 26-31, they do establish, I think, that the Government has a substantial degree of control over the use and disposition of the UGDP records.

B. Government Access

Under the HEW grant regulations, the Government has an apparently unlimited right of access to the UGDP raw data. 45 C.F.R. § 74.23(a) provides:

HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit, examination, excerpts and transcripts.¹⁰

¹⁰ The Government may have access to the UGDP raw data under FDA regulations as well. 21 C.F.R. § 312.1(a) (12) (6) (e) gives the FDA the right of access to investigator's records relating to investigational new drugs (INDs). The UGDP holds two INDs from the FDA. J.A. at 92. The federal defendants note that the regulation requires investigators to retain such records for only two years after administration of an IND has been discontinued, and assert that the UGDP discontinued use of its INDs more than two years ago. Gov. Br. at 34-35. However, there is no indication that

HEW is permitted to "examine" and "excerpt" not only the financial records of the UGDP, but also raw research records. This is demonstrated by the fact that when the FDA conducted a scientific audit of the UGDP, portions of the raw data were examined by government investigators, copied, and then retained by the agency. Gov. Supp. Memo. of Dec. 5, 1977.

The Government's right of access to the UGDP raw data is important for FOIA purposes since it establishes the basis for Government compliance with FOIA requests. Obviously, the Government must be able to obtain copies of requested agency "records" quickly and without legal impediment.¹¹ For example, if the Government had to purchase certain data, or subpoena certain records to comply with a FOIA request, these materials might not be considered agency "records." We need not decide this question, for no such barrier is involved here. The Government can exercise its right of access to the UGDP data at any time and for any reason. To be sure, greater inconvenience may be involved in obtaining copies of documents not in the immediate custody of the agency. But, as the Government concedes, agency "records" need not be located within the physical confines of the agency.

the UGDP has in fact discarded the records, or that the FDA right of access is extinguished two years after administration of an IND stops.

¹¹ The Act requires agencies to determine whether to comply with a FOIA request "within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request. . . ." 5 U.S.C. § 552(a) (6) (A) (1974). An additional 10 days is permitted in "unusual circumstances," including "(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request; . . ." *Id.* § 552(a) (6) (B) (i) (emphasis added). The last provision appears to specifically contemplate that agency "records" can be found outside the custody of the agency.

Gov. Br. at 20 n.32. Records may be bailed to a privately-owned warehouse, loaned to a private entity, or may have been sold or donated to the Government but not delivered. In terms of ease of compliance with FOIA, these types of situations are indistinguishable from the present case.¹²

C. Government Reliance

Probably the strongest link between the UGDP data and the Federal Government is found in the extensive history of federal reliance on the UGDP study and data in regulatory action dealing with the treatment of diabetes. This reliance must be viewed against the background of intense controversy surrounding the UGDP ever since the study's first conclusions were published in 1970.¹³

¹² The majority's assertion that *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 161-62 (1975) and *Renegotiation Board v. Grumman Aircraft Engineering Corp.*, 421 U.S. 168, 192 (1975) require more than a mere right of access to documents is without foundation. These cases stand only for the proposition that FOIA does not oblige an agency to write opinions. They say nothing about the duty to retrieve records that are reasonably described, admittedly exist, and are within an agency's power to obtain.

¹³ Klimt, Knatterud, Meinert & Prout, *The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes*, 19 DIABETES (Supp. 2) 747 (1970). Subsequent reports were published in Knatterud, Meinert, Klimt, Osborne & Martin, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: IV. A Preliminary Report on Phenformin Results*, 217 JAMA 777 (1971); Goldner, Knatterud & Prout, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: III. Clinical Implications of UGDP Results*, 218 JAMA 1400 (1971); Knatterud, Klimt, Osborne, Meinert, Martin & Hawkins, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes: V. Evaluation of Phenformin Therapy*, 24 DIABETES (Supp. 1) 65 (1975).

Release of the UGDP's initial findings, suggesting a possible correlation between oral hypoglycemic drugs and cardiovascular mortality, had a profound impact.¹⁴ Professional conferences were convened, articles were published, and scientific studies were undertaken with the hope of evaluating the UGDP conclusions and determining their validity. The medical and scientific communities eventually divided along pro- and anti-UGDP lines. Supporters of the UGDP cited the study's cost, duration, broad patient base, and sophisticated design as confirming the validity of the findings.¹⁵ Critics of the UGDP, on the other hand, pointed to alleged inadequacies in study design, methodology, and execution.¹⁶ The controversy was compounded when a UGDP investigator, Dr. Angela Bowen, resigned from the study, challenging the integrity of the program director and suggesting a possible manipulation of the data base to reach results unfavorable to one of the drugs under study.¹⁷

¹⁴ Some of the controversy surrounding the UGDP study is reviewed in the majority opinion at 3-7.

¹⁵ See, e.g., Cornfield, *The University Group Diabetes Program: A Further Statistical Analysis of the Mortality Findings*, 217 JAMA 1676 (1971); Prout, Knatterud, Meinert & Klimt, *The UGDP Controversy: Clinical Trials Versus Clinical Impressions*, 21 DIABETES 1035 (1972).

¹⁶ See, e.g., Feinstein, *Clinical Biostatistics: An Analytical Appraisal of the University Group Diabetes Program (UGDP) Study*, 12 CLIN. PHARMACOLOGY, THERAPEUTICS 167 (1971). Schor, *The University Group Diabetes Program: A Statistician Looks at the Mortality Results*, 217 JAMA 1671 (1971).

¹⁷ Dr. Bowen testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs:

An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has

Despite all the uncertainty about the validity of the UGDP study, and the inability of sceptical scientists and physicians to examine the raw data, the Federal Government has twice relied on the UGDP findings in regulatory action affecting a large segment of the public. In

also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators.

J.A. at 130-31.

1975, the Commissioner of the Food and Drug Administration (FDA) proposed new labeling requirements for oral hypoglycemic drugs used in the treatment of diabetes. 40 FED.REG. 28587 (1975). The *Federal Register* notice of the proposed warning stated in part:

The judgment of the Commissioner that changes must be made in the labeling of the oral hypoglycemic drugs to reflect the findings of the UGDP study is well known. . . .

The warning proposed in this labeling is based primarily on a thorough review and evaluation of the UGDP study. . . .

The Commissioner reaffirms his view that the UGDP study is an adequate and well-controlled clinical trial, which is the most extensive and detailed examination of the long-term administration of hypoglycemic agents yet undertaken.

. . . The Commissioner believes that the UGDP study is a validly conducted trial and accepts the opinion of the Biometric Society committee and other experts that the increased cardiovascular mortality found in this trial cannot reasonably be attributed to scientific shortcomings in the study.

Id. at 28591.¹⁸ A clearer affirmation and reliance on the UGDP study is hard to imagine.

¹⁸ The Commissioner of FDA recognized that "[f]rom the time the results of the UGDP study were first reported, the study was subjected to intense criticism by both clinicians and statisticians." 40 FED. REG. 28588. He conceded that "a wide-spread belief had developed among many physicians that the UGDP study was somehow flawed in terms of its design and execution, and therefore could not serve as a proper basis for a warning to the medical profession." *Id.*

The agency therefore decided to postpone implementation of the warning until [review of the UGDP study by

Later, in 1977, Secretary Califano of HEW declared phenformin, an oral hypoglycemic drug, an "imminent hazard to public health" under § 505(e) of the Food and Drug Act, 21 U.S.C. § 355(e), and suspended approval of all new drug applications for this drug. The Secretary indicated that he was relying to a considerable extent on the statistical evidence gathered by the UGDP. The order stated that "[t]he FDA, which is experienced in interpreting and analyzing incidence figures for adverse reactions, has examined [the UGDP] statistics and concluded that the incidence figures are scientifically valid."

a committee of the Biometrics Society] was published. Since the UGDP study was the basis for the proposed warning, the Commissioner believed that this independent review of the statistical validity of the study should be available to all interested persons before taking definitive action. The review by the committee of the Biometrics Society required extensive reanalysis of the data in the UGDP study and was not published until February 10, 1975.

Id. at 28589.

The Biometrics Society audit reconfirmed the Commissioner's belief in the need for regulatory action based on the UGDP.

Although the [UGDP] has shortcomings, which might be expected in any clinical trial of this complexity, the shortcomings do not invalidate the central finding that there appears to be an increased risk of cardiovascular mortality associated with the administration of tolbutamide and of phenformin to maturity-onset diabetic patients, compared to treatment with diet alone or diet plus insulin. This conclusion has in the past been reached independently by the UGDP investigators, the FDA, and the Biometrics Society committee, and is again affirmed by the Commissioner. Other clinical trials of these oral hypoglycemic drugs are not comparable to the UGDP study and provide insufficient evidence to negate the findings of the UGDP study.

Id. at 28591.

Order of the Secretary Suspending Approval at 11 (July 25, 1977).¹⁹

Significantly, the proposed labeling change and suspension of phenformin were not undertaken solely on the basis of the published studies of the UGDP. In addition, the Federal Government has twice exercised its right of access to the UGDP raw data to verify the validity of the UGDP findings. When the initial controversy over the UGDP erupted, NIAMDD retained an independent group of biostatisticians, the Biometric Society, to review the UGDP. The Society was given access to the UGDP raw data for this purpose. After conducting a partial audit, it published a report indicating support for the UGDP findings.²⁰ Several years later, prior to the suspension of new drug applications for phenformin, the FDA conducted its own audit of the UGDP. Details of this audit are sketchy, but the federal defendants admit that the FDA examined and copied at least a sample of the UGDP data in the course of its examination of the study. Gov. Supp. Mem. of Dec. 5, 1977 at 2.

These Government-sponsored or conducted audits are of considerable importance. By examining the UGDP raw data at first hand, the Government has apparently satisfied itself that the UGDP results are sound. In other words, the Government has relied *directly* on the UGDP raw data in the course of formulating official Government policy. As such, these data are precisely the sort of docu-

¹⁹ The quoted passage refers to statistics from "all available sources," Order at 11, but it is clear from the context that the UGDP is included. The UGDP is also referred to at pp. 8, 38, 40-41, 46, 63 and 66.

²⁰ Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents, *Report of the Committee for the Assessment of Hypoglycemic Agents*, 231 JAMA 583 (1975).

ments Congress intended to be disclosed under FOIA. *SDC Development Corp. v. Mathews*, *supra* n.3, at 1119-20.²¹

III.

The majority cryptically asserts that a finding that the UGDP raw data are agency "records" would interfere with the "autonomy" of federal grant recipients. The exact meaning of this is unclear. I do not maintain, nor do plaintiffs argue,²² that the UGDP is a federal "agency." Consequently, no suggestion has been made that all of the various duties and responsibilities of a federal agency should be imposed on the UGDP. The only question before us is whether the UGDP raw data are agency "records" of HEW. An affirmative answer to this question would require *HEW*—not the UGDP—to obtain copies of these records in response to plaintiffs' FOIA request. No direct interference with the manner or method in which a grantee conducts its research would result.

Perhaps the majority's reference to "autonomy" means to suggest that scientific activity would be chilled by the knowledge that data produced under a federal grant

²¹ In emphasizing the Government's reliance on the UGDP study and data, I do not imply that the court should give weight to plaintiffs' "need" for the UGDP raw data, or to plaintiffs' position as litigants in the phenformin suspension proceedings. Maj. Op. at 10-11. See *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975). My point is simply that, because of the Government's reliance, the UGDP data have been absorbed into the federal decision-making process. This factor, together with the factors previously mentioned—federal funding and federal right of access—satisfies me that the UGDP raw data are agency "records." They should therefore be potentially available for disclosure to *all* members of the public.

²² Plaintiffs do not challenge the district court's ruling, *see* n.4 *supra*, that the UGDP is not a federal "agency." Pet. Br. at 28 n.7.

could, in limited circumstances, become agency "records." This has been advanced elsewhere as a policy reason for not finding the UGDP data to be agency "records."²³ On closer examination, however, I think even this concern carries little force.

The notion that a chilling effect could result from subjecting the records of federal grantees to disclosure could refer to one of three things. First, it could refer to the possibly inhibiting effect of a visit to the laboratory by a federal official executing a FOIA request. As a basis for restricting FOIA, I find this implausible in the extreme. The inconveniences occasioned by an infrequent FOIA request would be no greater than those currently created by conditions attached to the grant, including the possibility of Government inspection.²⁴ Yet these burdens appear to have had an imperceptible effect on the enthusiasm for federal research grants.

Secondly, the chilling effect notion could refer to the danger that unscrupulous scientists would use FOIA to appropriate valuable research data for their own credit—or profit. This is a legitimate concern, and if all grantee research records were subject to FOIA it could conceivably deter some scientists from seeking federal grants. But the danger of misappropriation is minimal where, as here, the Government has relied on scientific records in the course of its decisionmaking. Government reliance will likely be limited to cases where the results of the study have been previously published or announced. Thus, whatever weight this concern is entitled to in other con-

²³ *Ciba-Geigy Corp. v. Mathews*, *supra* n. 3 at 530.

²⁴ As noted above, HEW grant regulations already give the Government an unlimited right to inspect grantee records. See pp. 7-8 *supra*. This right was in fact exercised in this case when the FDA audited the UGDP data.

texts, it is of little significance where the element of reliance is present.

Finally, federal grant applicants might be inhibited by having methodological or investigatory flaws in their work uncovered through a FOIA request. If *this* is the danger the majority seeks to avoid under the guise of protecting grantee "autonomy," then it is a sad day for both the scientific community and the Freedom of Information Act. The essence of the scientific community, I had thought, is the commitment to the advancement of scientific truth by subjecting findings and conclusions to the "exacting scrutiny of fellow experts."²⁵ Moreover, where scientific data bear the earmarks of agency "records" subject to FOIA, it would be the height of irony to deny disclosure on the ground that it could expose errors or frauds and thereby discourage those who do the work of the Government. FOIA was enacted in part to end the practice of withholding information "only to cover up embarrassing mistakes or irregularities. . . ." S.REP. No. 813, *supra*, at 3. To restrict the definition of agency "records" to accomplish the same end could only be regarded as a giant leap backwards.

I respectfully dissent.

²⁵ R. MERTON, *THE SOCIOLOGY OF SCIENCE* 275 (1973); see also B. BARBER, *SCIENCE AND THE SOCIAL ORDER* 89 (1952).

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United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 76-1308

PETER H. FORSHAM, et al., APPELLANTS

v.

JOSEPH A. CALIFANO, JR., Secretary of the Department of Health, Education and Welfare, et al.

On Petition for Rehearing

Filed October 17, 1978

Before: BAZELON, LEVENTHAL and MACKINNON, *Circuit Judges*

ORDER

Upon consideration of appellants' petition for rehearing, it is

ORDERED, by the Court, that the aforesaid petition for rehearing is denied.

Per Curiam

Circuit Judge Bazelon voted to grant rehearing for the reasons set forth in the attached statement.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Statement of BAZELON, Circuit Judge, as to why he voted for rehearing: In their petition for rehearing, the physicians who requested the UGDP data point out the unusual degree of federal involvement in the initiation and conduct of the UGDP study, which, even under the approach taken by the majority, would bring these data within the scope of "agency records." Specifically, plaintiffs suggest that rather than an independently conceived project by scientists who "developed their own methodology," *see* Maj. op. at 20, the UGDP study was in fact initiated by NIH, which was responsible for developing the research protocol. Petition for Rehearing at 4. Moreover, as a condition of the renewal of the UGDP grant, NIH established a Policy Advisory Board, which, according to plaintiffs, "took initiatives in directing the course of the [UGDP] study," further evidence of government involvement in the on-going UGDP research. *Id.* at 3-4.

The majority opinion notes that "where records are created by a private entity, we believe the applicability of FOIA will turn on whether the government is involved in the core planning or execution of the program." Majority op. at 16. Plaintiffs make a strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive.

Thus, in addition to the reasons set forth in my dissenting opinion, plaintiffs' contentions might well furnish an additional basis for finding these data to be "agency records." Plaintiffs could not previously have known precisely what showing was required under the majority's novel criteria for determining whether the data were agency records.¹ They have now raised a significant

¹ According to the majority, government involvement in the "core" of a program, *see* Maj. op. at 16 n.19, 21 is the key to determining whether records created by private individuals or groups are "agency records", which appears to be the first use of that concept in connection with the definition of agency

factual question which, under the majority's approach, warrants a remand to determine the degree of NIH involvement in the initiation and conduct of the UGDP study, rather than an affirmance of the district court, which had focused exclusively on the physical possession and ownership of records.²

records under FOIA. *Cf. Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977) where the district court, considering another FOIA request for the UGDP data noted that "[t]here is little official authority to aid the Court in discerning whether documents are agency records." *Id.* at 529. It is noteworthy that the principal authority which "lighted" the majority's path was not even a FOIA case, but an action under the Federal Tort Claims Act. See *Maj. op.* at 12-13, discussing *United States v. Orleans*, 425 U.S. 807 (1976).

² Admittedly, the contentions raised in the petition for rehearing are somewhat conclusory. If, however, the plaintiffs lack factual support sufficient to show government involvement in the core of the program, the district court will then be justified in dismissing the suit.

A far less satisfactory course would be to permit plaintiffs to elaborate their contentions on rehearing in this court. Such supplementation would not consist of adducing evidence, but would more closely resemble a proffer, designed to permit us to assess whether a remand in lieu of affirmance would be any more than a formal gesture. I believe that this approach is inferior to directly remanding this case to the district court because the questions involved are largely factual, and to explore them here may work substantial prejudice to both sides by denying them the opportunity to develop the relevant facts through further investigation, discovery and stipulation in the district court. Only with such a record can a court adequately judge the degree of NIH's involvement in the "core" of the UGDP study. However, I do not believe that we should cut off all avenues for the plaintiffs to show the requisite degree of government involvement in initiating and directing the UGDP study, and therefore I voted for rehearing.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Civil Action No. 76-1308

PETER H. FORSHAM, *et al.*, Appellants

v.

JOSEPH A. CALIFANO, JR., *et al.*

APPELLANTS PETITION FOR REHEARING,
AND IN THE ALTERNATIVE,
SUGGESTION FOR REHEARING IN BANC *

1. (Concise Statement of Issue and Its Importance)

At issue in this case is whether records derived from scientific research planned, financed and controlled by one government agency ad forming the basis for action by another government agency are not "agency records" under the Freedom of Information (FOI) Act, merely because the records are not housed within the physical confines of either agency. The records sought are the product of the University Group Diabetes Program (UGDP) study, a sixteen year study of diabetic patients and the effectiveness and hazards of various forms of treatment of these patients.

* Also submitted today for the consideration of the Court is Appellants' Motion to Protect Documents. Due to the completion of the UGDP study and the continued serious charges lodged against the coordinating center's handling of the data, there is a danger that the data which is the subject of this action may be destroyed. Such destruction would alienate Appellant's challenge of regulatory action based on the UGDP study data.

Filed today with the Clerk of the Court is a Motion for Expedited Hearing in *Forsham et. al. v. Califano* (U.S. Ct. App. D.C. Cir. No. 77-2072). This case involves agency action based on the UGDP study wherein production of the underlying data is a principle issue.

The records, or raw data of the UGDP study are a non-replicable public resource which are of great value to the nation's ten million diabetic patients. Whether this study's published results are truly consistent with the underlying clinical data is a question which has critical ramifications for diabetic patients.

Diabetes Mellitus is a progressive degenerative disease which dictates that treatment for the condition is a continual, daily battle to combat its effects. The UGDP study, through its published reports, would reach into the daily lives of each diabetic patient in the United States and foster a reliance on different modes of treatment. Every one of the presently available treatment modalities comes within the scope of the UGDP study. The results of the study have been and continue to be the subject of Federal regulatory action requiring changes in the diabetic patient's treatment regime.

Leading medical experts dispute the credibility of UGDP published reports. Serious charges of improprieties in the handling of the data continue to be lodged, even by grantee-investigators of the UGDP study itself. The requested public access, whether by confirming the study's results and removing doubts as to its reliability or by altering its conclusions and properly aligning life-saving diabetes therapy, would be of incalculable benefit to present and future victims of the disease.

The Court, in denying public access to the UGDP data, was apparently unaware of the extent to which the UGDP study was the product of government planning and operational control. Facts of the UGDP study relevant to a decision based on the new legal criteria for FOIA production in the Opinion of the Court have not been considered by the Court. Therefore, Appellants direct the Court's attention to the following factors which dictate a reconsideration of the request for public access to the UGDP study data.

2. Appellant-physicians are researchers who have received Federal grants to support their work. This background leads Appellants to appreciate the concern which the Court expressed for the independence and detachment from the government which the private researcher brings to his or her work. The autonomous grantee principle enunciated by the Court is deeply valued by Appellants. However, the UGDP study, as demonstrated below, was not the endeavor of an autonomous grantee.

(a) G. Donald Whedon, then Director of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), is cited by the Court (Opinion of the Court at p. 5) as describing the normal National Institutes of Health (NIH) grant situation as follows: "Supervision of the grantee's funded activities by this Institute is generally limited to review of periodic reports submitted by the grantee." However, for the UGDP study, NIH instituted a "Policy Advisory Board" as a condition for the renewal of the grant. This policy board was headed by Thomas C. Chalmer, M.D., an employee of NIH who had his offices at NIH and reported to the Director of NIH. With this in-house NIH leadership, the policy board took initiatives in directing the course of the study.

The clear governmental regulatory objective is also evident with the institution of the Policy Advisory Board. The policy board control of the study coincided with FDA application of the study results. The two factors of government control and regulatory use were closely linked in the UGDP study.

(b) Dr. Whedon of NIAMDD also stated "Furthermore, it is *not the normal practice* of NIH or this Institute to require grantees to submit their raw data for review and, in fact, submission of raw data to the Institute is *extremely rare*." (emphasis supplied) (Opinion of the Court, at p. 5) However, the UGDP study was not a normal NIH grant situation. NIH did require the UGDP co-ordinating center

to cooperate with the Biometric Society, an NIH contractor, to review the study data. The FDA, operating as the agent of NIH sent a team of investigators to the coordinating center to study the warehoused raw data. Defendants in this suit would deny the Plaintiffs access to the data because the data was so conveniently warehoused and located only several miles from NIH and FDA that actual removal of the raw data to government offices was not necessary.

(c) NIH's control over the study included initiation of the plan of research through a two year planning grant. The protocol of the study was the result of an NIH investment. The 12 UGDP university centers were carrying out a government program of research and the UGDP co-ordinating center was administering the study and storing the raw data. The resulting data at the co-ordinating center is not similar to the raw data of an autonomous grantee.

(d) The Opinion of the Court states, "Obviously a government agency cannot circumvent FOIA by transferring physical possession of its records to a warehouse or like bailer." However, just this kind of warehousing is involved with the UGDP co-ordinating center.

The Division of Epidemiology and Biostatistics of the Institute of International Medicine at the University of Maryland, the UGDP co-ordinating center, consisted of sixteen individuals whose primary duties involved co-ordinating federal grant research. The center also co-ordinated the NIH funded "Coronary Drug Project", serving as the data collection point for 53 clinical centers for nine years. The "Coronary Drug Project Aspirin Study" was a similar endeavor in which the Maryland center stored data on 1500 patients in that study. Additionally, the center served the same function as a data repository in the Diabetes Retinopathy Study, which involved 15 clinical centers and approximately 1600 patients. The UGDP study shared with the Diabetes Retinopathy Study its own office facilities that

were rented off campus and housed only these NIH funded activities. No patients were seen at the co-ordinating center.

Administrative storage and warehousing was the *raison d'être* for the co-ordinating center. Where, as here, the subject of an NIH grant is to collate and store data for analysis, public access does not violate the legitimate concerns of the grantee and, in fact, serves the purpose of the government funding.

3. For procurement of continued funding in 1975, the UGDP co-ordinating center submitted an Application for Supplemental Grant, in which study "close-out procedures" were outlined. These procedures stated that:

Once the UGDP investigators have completed their analyses, *the study data should become available for use by any qualified investigator.* In order for data to be available for use outside the UGDP, a group of UGDP investigators should be appointed to assume responsibility for reviewing and approving requests for data and for supervising the preparation and documentation of data tapes, disks, etc. Careful formulation and implementation of such procedures are necessary to assure proper distribution and utilization of study data. (Emphasis supplied)

These statements of the co-ordinating center demonstrate that public access to the raw data was to be a part of the grant plan. Far from eroding the concept of the autonomous grantee, Court ordered access would carry out the principles of scientific accountability which the UGDP itself acknowledged was a condition of the grant.

4. On page 12, the Opinion of the Court states that, "Insofar as it [HEW] is engaged through FDA, in a regulatory program, it may be subject to requirements of revelation which go beyond the FOIA's rules that govern all agencies. The FDA's regulatory actions are not before us in this FOIA lawsuit. . . ."

Appellants assert that FDA's regulatory actions are before the Court and impact on this FOIA request. The Commissioner of the FDA is a named party to the case and exercised the raw data audit rights of NIH as their agent. The FDA has relied on the study results for regulatory action affecting millions of diabetic patients. Additionally, if the UGDP grant funds had originated from the FDA, rather than its sister agency, NIH, the raw data of the study would be agency records under FDA regulation (21 C.F.R. 20.105(d)). In this case, where HEW through the FDA has applied the results of the study, and possessed the raw data of the study at the co-ordinating center, HEW would deny appellants access to the data because its other arm, NIH, funded the study. This theory would allow the government to limit the rights of the public through changing agency hats to fit the occasion.

It should be noted that the FDA does not shrink from the task of allowing public access to large numbers of documents from a scientific study. The Opinion of the Court therefore erred in placing undue weight on the "awesome implications" of such public access, especially in this case involving a unique set of facts and a 16 year non-replicable study.

5. Cases cited in the Opinion of the Court are not relevant to the facts of this case. *United States v. Orleans*, 425 U.S. 807, (1976) dealt with Federal tort liability, not the policy for disclosure of agency records. *NLRB v. Sears, Roebuck & Co.* is similarly not applicable here as no request has been made for the creation of agency records by Appellants. Since the requested records in the UGDP study are conveniently stored in a bank vault, copying of the records is a purely ministerial chore, unlike the situation in *NLRB v. Sears, Roebuck & Co.*

6. The Concurring Opinion, at page 2, states that no public harm will result from the denial of public access to UGDP data in view of the availability of subpoena au-

thority. However, the shortcomings of this suggested alternative and the further litigation it contemplates reinforces the importance of FOI access in this case. The situation with phenformin is illustrative. On July 25, 1977, the Secretary of Health, Education and Welfare declared phenformin an imminent hazard and summarily banned it from general use without prior hearing or disclosure of any of the raw data on which the order was based. This order was carried throughout the medical and lay press and caused confusion and alarm for thousands of diabetic patients and their physicians. While this order was challenged by appellants and others in concurrent administrative and judicial proceedings, these challenges are still pending at the present time, and no final decisions have been rendered.¹ In short, a full year after nearly all diabetics were required to be removed from phenformin on the basis of the UGDP, no forum—either administrative or judicial—has determined the merits of appellants' challenge to the order and in the context of that challenge, appellants' right to the UGDP raw data. Thus while after-the-fact litigation may theoretically be an alternative way of securing access to the data, it lacks the timeliness and expeditiousness of an FOI request as well as the capacity to prevent needless confusion, alarm and changes in treatment among diabetics and their physicians.

What appellants seek here through FOIA is to determine the validity of the UGDP study *before* further pre-emptory action is taken by the Government, not to wait for such action to occur and then challenge it after the fact. To require the public to await agency action and then sue the

¹ The phenformin administrative hearing process (Docket No. 77N-0150) is still ongoing due to the failure of FDA to issue a final ruling. Also pending are Appellants' challenge to the phenformin suspension order, *Forsham et. al. v. Califano*, at the District Court for the District of Columbia (No. 77-1478) and, on appeal to the Court of Appeals for the denial by the District Court of preliminary injunctive relief (No. 77-2072).

Government in order to learn of the basis for the Government's action, often taken without benefit of prior hearing, is antithetical to the fundamental principles of FOIA.

Respectfully submitted,

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Supreme Court, U. S.
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In the Supreme Court of the United States

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*ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS FOR
THE DISTRICT OF COLUMBIA CIRCUIT*

BRIEF FOR THE FEDERAL RESPONDENTS

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BRIEF FOR THE FEDERAL RESPONDENTS

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 4a-44a) is reported at 587 F. 2d 1128. The order of the district court (Pet. App. 45a-46a) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on July 11, 1978. A timely petition for rehearing was denied on October 17, 1978 (Pet. App. 1a). The petition for a writ of certiorari was filed on January 15, 1979. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether records generated by government grantees are "agency records" under the Freedom of Information Act,

where the agency does not own the records, does not possess them, and did not supervise their production.

STATEMENT

1. The Department of Health, Education, and Welfare granted funds to the University Group Diabetes Program (UGDP) to conduct a long-term clinical study of the treatment of diabetes.¹ In the course of the study, the group discovered that certain harmful effects appeared to result from the use of orally administered drugs to combat the disease (Pet. App. 5a, 9a). As a result of the study and a follow-up study conducted by the Biometric Society, a private organization of biostatisticians, the Food and Drug Administration proposed that changes be made in the labeling of oral hypoglycemic drugs and recommended that the use of those drugs be curtailed (Pet. App. 9a-10a).

2. Petitioners, a committee and several physicians specializing in the treatment of diabetes, filed Freedom of Information Act requests with the Department of Health, Education, and Welfare, seeking to obtain the raw data underlying the UGDP's report. The Department denied the request and informed petitioners that the raw data were the property of the institutions participating in the UGDP study (Pet. App. 11a).

Petitioners filed suit in the District Court for the District of Columbia, seeking to force the Department to comply with their FOIA request. The district court dismissed the complaint on the ground that neither the

¹The UGDP is a group of 13 private and state medical centers that had associated for the purpose of conducting the federally funded study (Pet. App. 6a-8a). The funds for the program were granted by the National Institute of Arthritis, Metabolism and Digestive Diseases, which is a part of the National Institutes of Health, which in turn is an organization within the Public Health Service of the Department of Health, Education, and Welfare (Pet. App. 6a).

Department nor any of its entities or employees were, or had ever been, in possession of the requested data. The court found that the data were the property of the UGDP study investigators and the UGDP coordinating center at the University of Maryland, and that neither the investigators nor the coordinating center is an "agency" covered by the Freedom of Information Act (Pet. App. 45a-46a).

3. The court of appeals affirmed, with one judge dissenting (Pet. App. 4a-44a). The court held, first, that the UGDP grantees are not federal agencies within the meaning of the Freedom of Information Act (Pet. App. 12a-13a). Second, the court held that the Freedom of Information Act does not require that an agency produce data in the possession of its grantees; only if the agency has created or obtained a record in the course of doing its work is there an agency record that can be demanded under the Act (Pet. App. 19a). Although the UGDP study group participants had agreed to be subject to audit by representatives of the Department, the court held that that agreement did not subject those participants to "accept rummaging by the world at large" under the Freedom of Information Act (Pet. App. 21a).

Judge MacKinnon concurred in the court's opinion, except for the portion suggesting that the Freedom of Information Act would apply not only to records in the possession of an agency but also to records the agency has a duty to obtain. As to records not in the possession of the agency, he stated, the applicability of the Freedom of Information Act should be determined case-by-case (Pet. App. 25a-26a).

Judge Bazelon dissented. He noted that the federal government provided all funding for the UGDP study, the government has an unrestricted right of access to the data, and the government has extensively relied on the UGDP study and data in regulatory action relating to the

treatment of diabetes. Under these circumstances, he concluded, the "degree of federal involvement with the UGDP raw data" is sufficiently great that they should be treated as agency records for the purposes of the Freedom of Information Act (Pet. App. 27a).

DISCUSSION

The question presented by this case is important for the administration of the Freedom of Information Act. Federal agencies contract with private entities in a variety of circumstances. Typically, the agency that grants funds to a private entity has some right of access to the records of that entity. If the Freedom of Information Act applies to documents held by a federal grantee because the agency has some right of access to the grantee's records, the effect on federal grant programs will be substantial.²

In our view, records of a federal grantee are not subject to disclosure under the Freedom of Information Act simply because the granting agency has a right of access to those records. The Act applies only to records that are in the custody or control of an "agency" at the time a disclosure request is made, and a grantee's receipt of federal funds does not turn it into a federal agency. *United States v. Orleans*, 425 U.S. 807 (1976).

It is well established that the Freedom of Information Act does not require agencies to create records; it merely requires the production of records in the agency's possession. See *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 162 (1975); *Renegotiation Board v. Grumman*

²"Right-of-access" provisions are common in federal grants and contracts. See, e.g., 21 C.F.R. 312.10; 32 C.F.R. 7-104.15; 45 C.F.R. 74.23(a). See also *Eli Lilly & Co. v. Staats*, 574 F. 2d 904 (7th Cir.), cert. denied, No. 78-190 (Nov. 6, 1978). It is fair to say that federal agencies have a right of access to many documents in the hands of almost everyone who deals with the federal government, and almost everyone deals with the federal government.

Aircraft Engineering Corp., 421 U.S. 168, 192 (1975). Similarly, the Act ordinarily does not authorize a court to order an agency to retrieve (or a non-agency to return) records that are no longer in the possession of an agency. The Freedom of Information Act simply entitles the requesting party to examine those agency records that are in the agency's possession at the time the request is made. See *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523, 531 (S.D.N.Y. 1977); *Nichols v. United States*, 325 F. Supp. 130, 137 (D. Kan. 1971), aff'd, 460 F. 2d 671 (10th Cir.), cert. denied, 409 U.S. 966 (1972). As was stated in the Attorney General's contemporaneous memorandum explaining the provisions of the FOIA, the Act "refers * * * only to records in being and in the possession or control of an agency. The requirement of this subsection imposes no obligation to compile or procure a record in response to a request." *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (June 1967).

Our submission that records must be in the possession or control of an agency in order to be subject to the mandatory disclosure requirements of the FOIA is consistent with the result reached by the court of appeals in this case. While the agency could have insisted on obtaining the records at issue in this case, it had not done so at the time of the FOIA request, and it had no duty to do so under the agreement between the Department and the UGDP grantee institutions. That is enough, we submit, to demonstrate that petitioners' claim must fail.

Petitioners argue that the court of appeals erred on several grounds in refusing to apply the Freedom of Information Act to the records at issue in this case. First, they contend (Pet. 15-19) that the district court erred in determining (Pet. App. 45a) that the UGDP raw data are the "property" of the UGDP investigators and grantee institutions, rather than the property of the United States.

Petitioners' contention is without merit. The government has never asserted title to the UGDP raw data. In none of the cases cited by petitioners was there any holding that raw research data generated by government grantees are government property, in the absence of an express or implied reservation in the grant documents. The general rule is that the working notes and data of professionals are their own and do not belong to the financial sponsor or client. See *Williams v. Weissner*, 273 Cal. App. 2d 726, 733, 78 Cal. Rptr. 542, 545 (1969); *Ablah v. Eyman*, 188 Kan. 665, 365 P. 2d 181 (1961).³ In any event, the question of proprietary interest does not govern the availability of records under the Freedom of Information Act. Even if particular records belong to an agency, they are not subject to disclosure if they are not in the custody and control of the agency at the time they are requested.

Petitioners next contend (Pet. 20-23) that records produced by government grantees are "agency records" (regardless of lack of possession or ownership) because they are produced "in fulfillment of" national goals. This argument is equally lacking in merit. All records produced by government grantees and contractors (and many documents produced by persons who are neither grantees nor contractors) are in some sense produced "in fulfillment of" national goals or objectives. But this does not mean that, when it enacted the Freedom of Information Act, Congress intended to vest the public at large with a right to require an agency to obtain and produce the records of government grantees and contrac-

³The cases cited by petitioners (Pet. 16-18) deal with title to property generated in an *employment* relationship, or in the course of a contract where the contractee either expressly or by implication had reserved title to valuable work product. They therefore are inapposite here. Petitioners also cite several HEW regulations (Pet. 19), but none reserves title to the raw data at issue here.

tors on demand. If Congress had meant to cast so broad a net, it would not have restricted the application of the Act to "agencies."

Finally, petitioners contend (Pet. 25-27) that the data at issue in this case should be deemed "agency records" because the FDA has proposed to take regulatory action based in part on the published results of the UGDP study. Petitioners' argument is, in effect, that the Freedom of Information Act extends to records of private or state government entities, where those records have formed the basis of a published monograph and where the federal government has chosen to rely on that published monograph as a basis for proposed regulatory action. Nothing in the Act supports such an expansive construction, and petitioners cite no authority in support of this contention.

Although we therefore believe that the judgment of the court of appeals is correct, we do not oppose the granting of the petition for a writ of certiorari. The question presented here is closely related to the principal question presented in *Kissinger v. Reporters Committee for Freedom of the Press*, No. 78-1088, and *Reporters Committee for Freedom of the Press v. Kissinger*, No. 78-1217, in which we have urged the Court to grant review.⁴ The cases present three aspects of a problem that is bound to recur until addressed by this Court: whether documents that are not in the possession of an "agency" nevertheless are subject to the FOIA. In No. 78-1088 the documents in question were generated within an "agency" but were removed before a request was made for their production; in No. 78-1217 the documents were created outside an agency, came into an agency's possession briefly, and then were removed before a request was made for production; here the documents never were in possession of an agency.

⁴We have provided a copy of our brief in Nos. 78-1088 and 78-1217 to counsel for petitioners.

The three cases together present the most important problems that are likely to arise concerning access to documents not in the possession of an agency. Because a substantial portion of all FOIA cases are litigated in the District of Columbia Circuit, and because there is no reason to conclude that additional appellate opinions addressing other facets of the question will be of assistance to the Court in its resolution, we believe that the Court should grant review here and address these recurring problems that affect every federal agency.

CONCLUSION

The petition for a writ of certiorari should be granted.
Respectfully submitted.

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MARCH 1979

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MICHAEL RODAK, JR., CLERK

IN THE
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Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
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DISTRICT OF COLUMBIA CIRCUIT

**BRIEF IN OPPOSITION OF RESPONDENT,
DR. CHRISTIAN R. KLIMT**

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ON PETITION FOR A WRIT OF CERTIORARI TO THE
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DISTRICT OF COLUMBIA CIRCUIT

**BRIEF IN OPPOSITION OF RESPONDENT,
DR. CHRISTIAN R. KLIMT**

The respondent, Dr. Christian R. Klimt, respectfully requests that this Court deny the petition for writ of certiorari, seeking review of the opinion of the United States Court of Appeals for the District of Columbia Circuit in this case. That opinion is reported at 587 F.2d 1128 (D.C. Cir. 1978).

QUESTION PRESENTED

Do raw data of a research study conducted by non-federal institutions, but funded by federal grants,

constitute "agency records" within the meaning of the Freedom of Information Act when the Government never controlled the research and never owned or possessed the raw data?

STATEMENT OF THE CASE

The petitioners seek review of the decision of the United States Court of Appeals for the District of Columbia Circuit that research data compiled by a non-federal group receiving money under a federal grant program do not become "agency records" under the Freedom of Information Act, 5 U.S.C. §552 (1976), merely because the Federal Government has funded the research program and has the authority to demand the production of the research data.

In 1959, twelve participating medical school clinics throughout the country (none of which are federal agencies or institutions) and a coordinating center at the University of Maryland formed the University Group Diabetes Program (the "Program") to conduct a long-term clinical study of the treatment of diabetes. The purpose of the study was to determine the relationship between the control of blood sugar in patients suffering from adult onset diabetes and the development of complications from this disease. To fund the study, the institutions participating in the Program obtained thirteen separate grants from the National Institute of Arthritis, Metabolism, and Digestive Diseases (the "Institute") of the National Institutes of Health; however, the physicians and scientists working for the participating institutions planned, designed, and conducted the study without the supervision or control of any federal agency.

The Program compiled data from the treatment of over 1,000 diabetic patients from 1961 to 1970 under four different treatment regimens; a fifth regimen was

included in 1963. Analyzing the data, the Program investigators concluded, among other things, that the administration of oral hypoglycemic drugs to certain adult onset diabetics led to a greater death rate from cardiovascular disease than was found in the groups not treated with such drugs. These findings were published in the Journal of the American Diabetes Association in December 1970.

In 1974, the petitioners asked the Institute for the raw data on which the study was based. Various officials of the Department of Health, Education, and Welfare advised them that, because no federal agency had any of the raw data, they were not able to grant the request. Subsequently, on July 5, 1975 the Commissioner of the Food and Drug Administration issued a notice of proposed regulations to require manufacturers of hypoglycemic drugs to include appropriate warnings in their labels. 40 Fed. Reg. 28,587 (1975).

Shortly thereafter, the petitioners filed an action in the United States District Court for the District of Columbia against the Secretary of Health, Education, and Welfare, other federal officials, and Dr. Klimt, Director of the Program's coordinating center at the University of Maryland, to obtain the research data. On February 5, 1976 the district court denied the petitioners' motion for summary judgment and granted the federal respondents' motion to dismiss. On appeal, the United States Court of Appeals for the District of Columbia Circuit affirmed.¹

¹ The respondent does not adopt the petitioners' statement of the case and has not responded at length to it because much of it is irrelevant to the issues before this Court. For example, the petitioner's alleged need for or interest in obtaining the data is irrelevant to whether the data are "agency records." *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975). The decision of the court of appeals accurately states the background facts in this case.

REASONS FOR DENYING THE WRIT

The court of appeals held that the raw data gathered during the study by the Program, formed by thirteen non-federal institutions, were not federal agency records within the meaning of the Freedom of Information Act. The court reasoned that the funding of the study by the Federal Government, which exercised no control over the performance of the study, did not convert the Program's participants into federal agencies. The court also concluded that, although the Federal Government may have the right of access to the raw data, the Freedom of Information Act did not require the Federal Government to exercise whatever right of access it may have to obtain the raw data and thereby to make them "agency records." In addition, the court held that the Government's right of access by itself did not transform the data into "agency records."

Thus, the court determined a narrow issue of interpretation of the Freedom of Information Act. Because the decision of the court of appeals does not conflict with the decisions of any federal court on this issue, because it is in complete harmony with the principles enunciated by this Court and lower federal courts, and because the issue in this case is not an important question of federal law requiring resolution by this Court, the petition for a writ of certiorari should be denied.²

² The respondent is aware that, contemporaneously with its consideration of this petition, the Court is considering petitions seeking review of the unrelated decision of the United States Court of Appeals for the District of Columbia Circuit in *Reporters Committee for Freedom of Press v. Vance*, No. 78-1207 (5th Cir. Nov. 7, 1978), *petitions for cert. filed*, No. 78-1088 (Jan. 8, 1979); No. 78-1217 (_____, 1979). The decision of the court of appeals in *Vance* affirmed the judgments of the district court. The district court held that transcriptions of telephone conversations between former Secretary of State Kissinger and others, which were produced in accordance with regulations of the Department of State

I.

THE DECISION OF THE COURT OF APPEALS DOES NOT CONFLICT WITH THE HOLDINGS OR PRINCIPLES OF THE DECISIONS OF THIS COURT OR OTHER FEDERAL COURTS.

In determining that the raw data of the Program's study are not agency records within the meaning of the Freedom of Information Act, the court of appeals relied on well-established principles of law stated by this Court, the courts of appeals, and district courts. The court of appeals neither deviated from these principles nor announced new principles in conflict with any of these decisions. For this reason alone, the decision of the court of appeals should not be reviewed by this Court.

For example, the United States District Court for the Southern District of New York reached an identical conclusion that the raw data of the Program's study were not agency records within the meaning of the Freedom of Information Act. *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977). In that case, the district court concluded that neither the Program nor the individuals or institutions participating in the Program had any authority in law to make decisions for a federal agency. The court also held that the degree of governmental involvement in the opera-

and on Government time with the aid of departmental employees, equipment, materials and other public resources, were the property of the United States and not the personal property of Mr. Kissinger and that the plaintiffs had withdrawn their claim to Mr. Kissinger's notes of conversations conducted in his capacity as National Security Advisor. *Reporters Committee for Freedom of Press v. Vance*, 442 F. Supp. 383 (D.D.C. 1977).

It is clear that the petitions in the cases concerning Mr. Kissinger's notes involve entirely different issues from the question presented in this case. Accordingly, this Court's determination of whether to grant review in those cases should not affect its consideration of the petition in this case.

tions of the Program was insufficient to make the Program an agency for purposes of the Act. 428 F. Supp. at 528.

This conclusion is completely consistent with the purpose of the Freedom of Information Act. As the district court stated in *Lombardo v. Handler*, 397 F. Supp. 792, 802 (D.D.C. 1975), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976) (*mem.*), *cert. denied*, 431 U.S. 932 (1977):

The strength of the [Act] is the concept of public accountability for the operation of federal agencies. It was not intended to be applied directly to private entities which merely contract with the government to conduct studies.

In *Lombardo*, the court held that the National Academy of Sciences and its committee on motor vehicle emissions, which had contracted with the Administrator of the Environmental Protection Agency to conduct studies relating to certain emission standards established under the Clean Air Act, were not federal agencies.

When faced with a question of whether a particular entity is a federal agency within the meaning of the Freedom of Information Act, the courts have determined whether the entity has any authority in law to make decisions, *Washington Research Project, Inc. v. Department of Health, Education, and Welfare*, 504 F.2d 238, 248 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 963 (1975) (holding that initial review groups composed of non-governmental specialists established to assist the Government in evaluating proposals for research grants are not federal agencies), or whether the entity is subject to substantial federal control over its day-to-day operations, *Rocap v. Indiek*, 539 F.2d 174, 177 (D.C. Cir. 1976) (holding that the Federal Home Loan Mortgage Corporation is a federal agency). Similarly, whether a particular entity is a federal agency for other purposes generally depends upon the degree of control that the

Federal Government exercises over that entity. *United States v. Orleans*, 425 U.S. 807, 818 (1976) (holding that a local community action agency is not a federal agency and that its employees are not federal employees within the meaning of the Federal Torts Claims Act); *Spark v. Catholic University*, 510 F.2d 1277, 1282 (D.C. Cir. 1975), and *Wahba v. New York University*, 492 F.2d 96, 102 (2d Cir.), *cert. denied*, 419 U.S. 874 (1974) (both holding that private universities are not subject to constitutional restrictions applicable to the Government). Furthermore, as these cases hold, the mere receipt of federal funds by the non-governmental entity does not convert a private entity into a federal agency. The court of appeals did nothing more than correctly apply these principles to the facts in this case.

Before the court of appeals and in their petition, the petitioners suggest that the right of access to the raw data which the officials of the Department of Health, Education, and Welfare enjoy pursuant to 45 C.F.R. § 74.23(a) (1977) makes the raw data agency records. As the court of appeals concluded, this argument is without merit. There is nothing in the Freedom of Information Act to suggest that a federal agency's right to obtain information in private hands transforms that information into agency records.

Furthermore, this Court recognized this very principle in *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975). In *Sears*, this Court held that the Freedom of Information Act did not compel federal agencies to produce or create material or to write opinions in cases in which they would not otherwise be required to do so.

[The Act] only requires the disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

Id. at 161-62. Consequently, because there is no conflict between the decision of the court of appeals and the decisions of this Court and other federal courts, this Court should deny the writ of certiorari.

II.

THE ISSUE DECIDED BY THE COURT OF APPEALS IS NOT AN IMPORTANT QUESTION OF FEDERAL LAW REQUIRING RESOLUTION BY THIS COURT.

Notwithstanding the petitioners' hyperbole about broad implications for millions of diabetic patients, petition at 14, the decision of the court of appeals has very little significance for diabetic patients who may be affected by the actions of the Secretary of Health, Education, and Welfare or the Commissioner of the Food and Drug Administration.

The court of appeals itself recognized the limited impact of its decision. It specifically stated that its ruling had no effect on whether the petitioners would have a right of access to the raw data in any existing or future proceedings by the Commissioner of the Food and Drug Administration. Furthermore, it recognized that the appropriateness of the action of the Commissioner and the availability of the raw data in any proceedings before the Commissioner were distinctly different issues from the issue before the court. 587 F.2d at 1134.

In addition, the availability or non-availability of the data to the petitioners has very little direct impact upon the action of the Commissioner in requiring manufacturers of hypoglycemic drugs to include certain warnings in their labels. The Commissioner decided to issue the proposed regulation not because he had accepted without question the results of the study but rather, even assuming certain flaws in the Program's study, the findings of the study did raise a serious

question about the risk associated with the use of such drugs. 40 Fed. Reg. 28,587, 28,591 (1975).

Even if the petitioners were to obtain access to the raw data and were able to derive different conclusions from that data than did the Program, the Commissioner would not be required to rescind the proposed regulations. The Commissioner might have to evaluate the analysis which the petitioners would propose, but he would have the responsibility to make a judgment based upon all of the available evidence and the opinion of the experts who interpreted that evidence. Even with a contrary analysis by the petitioners, the Commissioner might still require the warnings, on the basis of the Program's study. Thus, although the outcome of the continuing debate in which this case plays a small part may have broad implications for diabetic patients, the impact of the decision of the court of appeals is itself negligible. In view of the unanimity of federal court decisions on the principles by which the court of appeals was guided, this case does not present a significant question of federal law which this Court should address.

CONCLUSION

For these reasons, this Court should deny the petition for a writ of certiorari.

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On Writ of Certiorari to the United States Court of Appeals
For the District of Columbia Circuit

BRIEF FOR PLAINTIFF-PETITIONERS

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IN THE
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No. 1118

PETER H. FORSHAM, ET AL.,
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v.

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Defendant-Respondents.

On Writ of Certiorari to the United States Court of Appeals
For the District of Columbia Circuit

BRIEF FOR PLAINTIFF-PETITIONERS

CITATIONS TO OPINIONS BELOW

The Opinion of the Court, Concurring Opinion and Dissenting Opinion of the United States Court of Appeals for the District of Columbia Circuit are not officially reported and are set out in the Appendix at pp. 217, 238, and 240 respectively. The unreported Statement of Circuit Judge Bazelon as to why he voted for rehearing is set out in the Appendix at p. 259. The Order of the United States District Court for the Dis-

trict of Columbia granting respondents' Motion to Dismiss is set out in the Appendix at p. 180.

JURISDICTION

The Judgment of the United States Court of Appeals for the District of Columbia Circuit was entered on July 11, 1978. The Petition for Rehearing and the Suggestion for Rehearing En Banc were denied on October 17, 1978. Jurisdiction of this Court was invoked under 28 U.S.C. § 1254(1) to review the decision of the United States Court of Appeals for the District of Columbia Circuit by Petition for a Writ of Certiorari filed January 15, 1979. The Petition for a Writ of Certiorari was granted by this Court on May 14, 1979.

QUESTIONS PRESENTED

1. Whether records derived from a scientific study funded entirely by an agency of the federal government which was also significantly involved in the planning, implementation, and monitoring of the study constitute "agency records" under 5 U.S.C. § 552.

2. Whether records of government funded research which, by contract and regulation, are fully available for government access and have in fact been partially audited by and at the direction of the government, are "agency records" under 5 U.S.C. § 552.

3. Whether records of government funded research which have been absorbed into the decision-making process of a government agency, and form the basis for its regulatory action, are "agency records" under 5 U.S.C. § 552.

STATUTES AND REGULATIONS INVOLVED

This is an action brought under the Federal Freedom of Information Act (FOIA), 5 U.S.C. § 552, to order the production of agency records improperly withheld. Also directly pertinent to this action and the records sought are certain United States Department of Health, Education, and Welfare regulations governing the administration of grant research and the Federal Food and Drug Administration regulations governing the maintenance and disclosure of records. The statute and regulations are set forth, in pertinent part, in the appendix to plaintiff-petitioners' brief.*

STATEMENT OF FACTS

Introduction

Plaintiff-petitioners (hereinafter petitioners) are three physicians who are members of the Committee on the Care of the Diabetic (CCD), an association of more than 200 physicians throughout the United States who are involved in the daily management and treatment of patients suffering from adult-onset diabetes mellitus, a disease affecting millions of Americans. Petitioners, and substantial numbers of the CCD members they represent, are active medical practitioners and leading researchers and educators in the field of diabetology.

At issue is petitioners' right of access under the Freedom of Information Act (FOIA) to identifiable collected data generated in the course of a unique scientific study known as the University Group Diabetes Pro-

* Three years have elapsed since the Appendix was prepared for the proceedings below. In order to provide the Court updated scientific, administrative and regulatory information, a separate appendix is included at the conclusion of plaintiff-petitioners' brief (hereinafter cited as App. Br.).

gram (UGDP). Subsumed within the legal issue is a fundamental scientific concern; that is, that scientific inquiry and the scientific method depend upon peer access to and analysis of a study's underlying data whenever legitimate scientific controversy arises over the study's reported findings. Only through such access and analysis can the study's validity or lack thereof be determined.¹

The University Group Diabetes Program

The UGDP is a collaborative effort involving twelve diabetes clinics around the country and a computerized Coordinating Center at the University of Maryland. It was originally formed in 1959 as a result of a two-year planning grant from the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD). Beginning in 1961 and continuing to 1978, the UGDP was awarded a series of NIAMDD grants totalling approximately fifteen million dollars, the purpose of which was to study the effectiveness of four different treatment regimens² in preventing the principal complications of diabetes mellitus.³ NIAMDD grants constituted the sole source of UGDP funding.

¹ A recent perspective of the UGDP study, its design, goals and controversial history has appeared in *SCIENCE*, the Journal of the American Association for the Advancement of Science. "Controversy Over Study of Diabetes Drugs Continues For Nearly A Decade," 203 *SCIENCE* 986 (1979). The text of this article is reproduced in App. Br. 1a.

² The four regimens were: diet (plus placebo) alone, diet plus a fixed dose of an oral hypoglycemic drug (tolbutamide), diet plus insulin in a fixed dosage, and diet plus insulin in a variable dosage. A fifth schedule was subsequently added involving diet plus a fixed dosage of phenformin, another type of oral hypoglycemic drug.

³ The principal complications are cardiovascular disease, retinopathy, nephropathy and neuropathy.

More than one thousand patients were enrolled, treated, and followed at the twelve clinics, using a system of double blind controls, i.e., neither patient nor physician knew which particular regimen the patient was receiving. To assess the relative efficacy of the treatments under investigation, the results of the various tests administered at the beginning of the study and on a quarterly basis thereafter were recorded onto standardized forms and forwarded from each of the clinical centers to the UGDP Coordinating Center at the University of Maryland. There, they were collected, coded, keypunched, and transferred onto magnetic discs and tapes to permit rapid computer access and analysis. It is these standardized reporting forms, in their original form and as processed for computer purposes by the Coordinating Center, that constitute the UGDP raw data sought here.

NIAMDD maintained a direct and close involvement with the UGDP as the study progressed. In addition to reviewing and approving UGDP progress reports on a regular basis and awarding UGDP renewal funding annually, NIAMDD established a number of special mechanisms for monitoring and directing the course of the UGDP as it developed. Employees of NIAMDD actively participated in these activities. See pp. 32 to 34 *infra*.

Starting in 1968, the FDA established direct contact with the UGDP, particularly after early data analyses at the Coordinating Center suggested the statistical possibility of an excess mortality in patients assigned to the drug tolbutamide as compared to the other study regimens. The FDA's Medical Advisory Board recom-

mended that the agency "review the raw data and continue in close contact with the UGDP."⁴

However, no agency review of the raw data took place and, in the Spring of 1970, the FDA received from the UGDP an advance copy of its report. The principal conclusion of the report was that the combination of diet and oral hypoglycemic medication was no more effective than diet alone in prolonging life, and that there was a possible correlation between oral medication and cardiovascular mortality.⁵ To evaluate the report, the FDA convened an *ad hoc* committee consisting of FDA staff, UGDP investigators, and five outside consultants who were specialists in the treatment of diabetes. At their meeting, held on May 21, 1970, the consultants had serious reservations about the study and refused to endorse it.⁶ Nonetheless, even before the meeting had adjourned, articles announcing the UGDP conclusions appeared in the lay press.⁷

⁴ Oversight Hearings Before the Subcommittee on Intergovernmental Regulations of the House Committee on Government Operations, 91st Congress, 2nd Session (Statement of Charles C. Edwards, M.D., Commissioner of Food and Drugs, at 15) (June 9, 1970).

⁵ The formal publication of the report first appeared in November of 1970. Klimt, Knatterud, Meinert & Prout, "The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients With Adult-Onset Diabetes," 19 DIABETES 747 (Supp. 2) (1970).

⁶ "Controversy Over Study of Diabetes Drugs Continues For Nearly a Decade," 203 SCIENCE 986, 987 (1979) (See App. Br. 4a).

⁷ See, e.g., "Diabetes Pills—A Killer?," New York Post, May 21, 1970; "Anti-Diabetes Pills Held Causing Earlier Death," The Washington Post, May 21, 1970.

Press accounts of the UGDP conclusions triggered immediate and grave concern on the part of diabetic patients and their physicians who knew little about the UGDP. Professional conferences were convened, scientific articles were published and additional studies, albeit of a more limited scope, were undertaken in the hopes of evaluating the UGDP conclusions and determining their validity. Rather quickly, the dialogue turned into a debate with the medical and scientific communities sharply divided along pro- and anti-UGDP lines. Supporters of the UGDP pointed to the study's cost, duration, broad patient base, and sophisticated design to confirm the validity of the findings.⁸ UGDP critics, on the other hand, cited numerous inadequacies in study design, methodology, and execution, not the least of which was an apparent breakdown in initial randomization which led to a far greater predisposition to cardiovascular risk in hypoglycemic-treated subjects than in control group subjects.⁹

The scientific debate took on an added dimension when Dr. Angela Bowen, a UGDP investigator, challenged the integrity of the study's data base and re-

⁸ For example:

Cornfield, "The University Group Diabetes Program: A Further Statistical Analysis Of The Mortality Findings," 217 JAMA 1676 (1971).

Prout, Knatterud, Meinert, et al., "The UGDP Controversy: Clinical Trials Versus Clinical Impressions," 21 DIABETES 1035 (1972).

⁹ For example:

Feinstein, "Clinical Biostatistics: VIII. An Analytical Appraisal Of The University Group Diabetes Program (UGDP) study," 12 CLINICAL PHARMACOLOGY 167 (1971);

Schor, "The University Group Diabetes Program: A Statistician Looks At The Mortality Results." 217 JAMA 1671 (1971).

signed from the study when her request to examine the raw data was denied.¹⁰ Since all data analyses had been conducted at the Coordinating Center under the direction of defendant-respondent Christian R. Klimt, and since all UGDP reports had been prepared at the

¹⁰ Dr. Bowen testified as follows before FDA at the public hearings on the proposed labeling change for oral hypoglycemic drugs on August 20, 1975:

An even more troublesome aspect has not been as well explored. This involves the matter of personal integrity and scientific honesty of one key member of the group. This question was actively considered both privately and openly among the investigators as early as 1968. It has also been asked publicly since that time. The question that the FDA must now ask and hopefully answer is "Were the data that were gathered in the field accurately and honestly recorded and reported from the coordinating center in Baltimore?" I fully recognize that this is a serious allegation but there is basis for reasonable doubt. You will recall that this was a double blind study. Investigators did not know what medication a patient was taking. Data were simply recorded and sent along to the biostatistician at the coordinating center. We then received a printout of the cumulative results. Therefore if one was told that a given death or other side effect occurred in a tolbutamide patient it was taken on faith because the investigator never knew for sure. [Tolbutamide is an oral hypoglycemic drug and a competitor of phenformin.] It did not occur to me to question this state of affairs until 1968 when the first allegation was made that the death rate was higher in the tolbutamide group. At the same meeting another investigator revealed that the biostatistician, Dr. Klimt, was a paid consultant to U.S. Vitamin, the then makers of phenformin. This was at first denied, then acknowledged. A spirited discussion followed during which the potential for abuse under such circumstances was discussed at length. This ended with the demand from the New York delegation that an independent review of the data be undertaken by outside statisticians. Dr. Klimt threatened to resign if this was done. This threat did not meet with universal disapproval, but a compromise was finally reached in which a review would be done but Dr. Klimt would be permitted to choose the reviewers! Drs. Cornfield and Brown were his choices. It is my understanding that they simply reviewed the numbers and methods sent to them by the coordinating center and that raw data were not used even then. This episode caused a rift of major proportions among the investigators. (A. 153-154)

Center, this challenge to the Coordinating Center and the raw data went directly to the validity of the UGDP's reported findings.

FDA's Adoption of the UGDP

From May 1970, despite the absence of any medical or scientific consensus regarding the UGDP, the FDA began issuing Reports and Drug Information Bulletins to physicians around the country, setting forth the agency's revised position on the proper treatment of diabetes.¹¹ This action was based entirely on the UGDP.

CCD was organized immediately thereafter in an attempt to assure that both diabetic patients and their physicians were provided with full, accurate, and truthful information concerning the safety and efficacy of the various treatment modalities. Petitioners became concerned that such premature FDA recommendations had created needless anxiety for diabetics and confusion for their physicians. In a December 1, 1970 telegram to the FDA entitled a "Statement on the Treatment of Diabetes," petitioners stated that physicians had been provided no basis for making their own assessment of the validity of the UGDP and requested that

before any further action is taken by regulatory agencies, the [UGDP] raw data should be made available to the scientific community at large (A. 7).

In a subsequent exchange of correspondence with FDA, petitioners renewed their request for an inde-

¹¹ Much of the early history of FDA's adoption of the UGDP is related in 40 Fed. Reg. 28589 (1975).

pendent review of the raw data. Nevertheless, the FDA endorsed the UGDP findings based on an allegedly full and careful evaluation of the study without responding directly to petitioners' request.¹²

Shortly thereafter, the FDA proposed relabeling of all oral hypoglycemic drugs to reflect UGDP conclusions. Petitioners formally petitioned the FDA to rescind its proposal and to withhold further action pending independent corroboration of the study. In their petition, petitioners presented a detailed critique of UGDP conclusions and again requested access to the raw data both for themselves and for other qualified researchers:

The failure to release the basic data and patient records so long sought by the scientific community has made it impossible to draw final conclusions about the study and the purpose of this critique is to raise the questions precipitated by the data which has been released. CCD Petition to FDA (October 7, 1971).

¹² The unavailability of the raw data was a pivotal factor in the icy reception the UGDP results received abroad when they were published. The following scenario is described when Dr. Klimt first presented the UGDP findings to the German Diabetes Association in Dusseldorf, West Germany in 1970:

The burden of presentation of the UGDP viewpoint fell mainly on Dr. Klimt. The members of the German host group kept raising pertinent questions to which, apparently, they did not have adequate responses. Thereupon, a spokesman for the German group said, "We're asking you a simple question: if we ask for access to the raw data in Baltimore can we see it?" To this Dr. Klimt responded, "No!"

As a result, the UGDP was not endorsed by the German, Canadian, British, or Swedish Governments.

Cooper, "The Use of Outside Advisory Sources in Regulatory Decision-Making on Drugs", p. VI-8, (1971) (published by the Interdisciplinary Communications Program, Smithsonian Institution, March 1971).

FDA denied the petition on June 5, 1972, and again fully endorsed the UGDP. In response to petitioners' request for access to the raw data, the FDA responded:

Your petition states that the results of the UGDP study are not available and therefore not subject to the usual critical review. *We have been assured that the UGDP personnel will honor any reasonable request for data and information.* Letter from Charles C. Edwards, M.D., FDA Commissioner, to Neil L. Chayet (June 5, 1972) (emphasis supplied).

However, personnel at the Coordinating Center were not responsive to requests for access to the raw data, even from investigators associated with the UGDP (A. 155). Consequently, when the FDA reinitiated its attempts to require relabeling of oral hypoglycemic drugs based solely on the UGDP, petitioners brought an action in the United States District Court for the District of Massachusetts to enjoin such relabeling and to require production of the raw data. *Bradley v. Richardson* (72-2517-M, 1972). A preliminary injunction issued enjoining the proposed relabeling, from which order the FDA appealed. In its opinion on July 31, 1973, the First Circuit Court of Appeals remanded the labeling question to the FDA while discussing, in dicta, petitioners' entitlement to the raw data as being part of the administrative record. *Bradley v. Weinberger*, 483 F.2d 410, 414 note 4 (1st Cir. 1973).

The Biometric Report

At this point, the FDA deferred regulatory action on the oral hypoglycemics pending a report from a group of outside biostatisticians known as the Bio-

metric Society (Biometrics). At the request of and under contract with NIAMDD, Biometrics reviewed the statistical, as opposed to clinical, quality of the UGDP. It had been "urged" by NIAMDD

to utilize all the resources it need[ed] to arrive at a satisfactory answer . . . Although no prior approval by the NIH is required, we shall expect to be kept informed of the conclusions as they develop.¹³

The fact that the Biometrics Report did not issue for two and one-half years contributed to rumors of sharp division among its members along familiar pro- and anti-UGDP lines. Petitioners were informed that Biometrics had actually prepared an earlier draft of its report which NIAMDD opposed due to its criticism of the Institute sponsored study. The final Biometric Report endorsed many of the arguments on both sides of the controversy and concluded with "moderately strong" support for the UGDP.¹⁴

Particularly relevant for purposes of this action is that, by contract with NIAMDD, Biometrics was given direct access to *all* of the UGDP raw data in the course of preparing its Report. While Biometrics actually reviewed only portions of the available data, this was a self-imposed limitation which, to many, di-

¹³ Letter from Robert Q. Marston, Director of NIH, to Colin White, Committee Chairman, June 9, 1972, quoted in "Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents", 231 JAMA 583, 585 (1975) (hereinafter Biometric Report).

¹⁴ *Id* at 599.

minished the ultimate value of the Report.¹⁵ With the Biometrics findings in hand, the FDA once again proposed relabeling of the oral hypoglycemics.¹⁶

FOIA Requests

Since the FDA resumed regulatory action based on the Biometrics Report, a report prepared following direct access to the raw data, petitioners initiated a series of FOIA requests for the same access to the raw data and for a copy of the draft Biometrics Report. These requests were directed to the various agencies within HEW which had been involved with the UGDP. The correspondence back and forth consumed a period of seven months:

- Request of October 14, 1974 to NIAMDD; Denied on October 21, 1974 (A. 40-41);
- Request of November 4, 1974 to FDA (A. 42); Forwarded to the Public Health Service on November 11, 1974 (A. 44-45);
Forwarded from the Public Health Service back to NIAMDD on November 22, 1974 (A. 46);
Forwarded to HEW and denied on December 3, 1974 (A. 47-48);
- Request of January 2, 1975 to HEW for administrative review and reconsideration; No Action re UGDP data (A. 49-54);
- Request renewed on May 6, 1975; Denied on May 23, 1975 (A. 55-58).

¹⁵ For example: Bradley, "Settling the UGDP Controversy?" 232 JAMA 813 (1975); O'Sullivan, "Decisive Factors in the Tolbutamide Controversy," 232 JAMA 825 (1975).

¹⁶ 40 Fed. Reg. 28582 (1975).

Finally on August 7, 1975, following an exchange of further correspondence, the Assistant Secretary for Health of HEW, Dr. Theodore Cooper, notified petitioners of the following:

- That neither the UGDP sponsor (NIAMDD) nor the agency proposing regulatory action based on the UGDP (FDA) had ever reviewed or even seen the raw data;
- That FDA's proposed relabeling action was based solely on the published reports of the UGDP and not on its own analysis of the data;
- That the raw data were now secured in a Maryland bank vault under the control of Dr. Klimt and;
- That, in HEW's view, such data were the property of the Coordinating Center and the UGDP investigators and that HEW had no authority to require the data to be made available in any form other than published reports (A. 68-69).

Immediately upon receipt of this statement, petitioners notified HEW of their intention to seek judicial relief, having exhausted administrative remedies (A. 70-71).

District Court Proceedings

On September 30, 1975, petitioners filed a complaint under the FOIA seeking production of the UGDP raw data and the draft Biometrics Report. The complaint also sought a judgment that the withholding of the requested records by both the federal respondents and respondent Klimt was unlawful (A. 3). Accompanying the complaint were affidavits of the petition-

ers (A. 12-16) documenting the scientific controversy surrounding the UGDP study, the efforts petitioners had taken to discover the scientific facts of the matter, and the importance of the raw data to those efforts. Also appended were exhibits chronicling the exchange of communications with the federal respondents (A. 18-95, 111-114).

On November 21, 1975, the federal respondents moved for dismissal and/or summary judgment. Accompanying their pleadings were affidavits of the Assistant Secretary for Health for HEW and the Director of NIAMDD which stated that no officer or employee within HEW or its sub-agencies had ever seen the raw data and that in their judgment, such data were not agency records under the provisions of FOIA (A. 140-148).

Respondent Klimt filed separate pleadings, moving to dismiss petitioners' complaint and to quash service of process on the grounds of lack of jurisdiction over the person and insufficiency of process (A. 116). Petitioners opposed the motions of respondent Klimt (A. 118), and filed an opposition to the motions of the federal respondents while moving for summary judgment and hearing (A. 151).

On December 16, 1975, FDA announced its intention to audit the UGDP raw data (New York Times, December 17, 1975), a fact of which petitioners asked the District Court to take judicial notice during the course of oral argument.

On February 5, 1976, the Court dismissed petitioners' complaint for FOIA relief against the federal re-

spondents and granted federal respondents' motion to dismiss, ruling that:

- (1) no official or employee of HEW, NIH, FDA, or NIAMDD had ever been in possession of the UGDP raw data;
- (2) the raw data were the property of the individual investigators and UGDP study Coordinating Center and remained in the possession, custody and control of the UGDP study Coordinating Center;
- (3) neither the individual investigators nor the UGDP study Coordinating Center was an "agency" under FOIA;
- (4) consequently, the raw data in issue were not "agency records" subject to FOIA (A. 180).

On February 25, 1976, petitioners appealed the denial of FOIA relief to the United States Court of Appeals for the District of Columbia. At oral argument before the Court of Appeals on December 2, 1976, counsel for federal respondents confirmed that the FDA had undertaken an audit of the UGDP raw data and that all materials gathered during the course of the audit would be provided to petitioners in response to their FOIA requests.

When no audit materials were forthcoming, petitioners once again filed a formal FOIA request with the FDA.¹⁷ After a five-month exchange of correspondence,¹⁸ petitioners received a set of documents pur-

¹⁷ Letter from Neil L. Chayet to J. Richard Crout, M.D., Director of FDA Bureau of Drugs (January 5, 1977).

¹⁸ Letter from J. Richard Crout, M.D., Director of FDA Bureau of Drugs to Neil L. Chayet (February 9, 1977); Letter from Neil L. Chayet to Donald Kennedy, FDA Commissioner (May 5, 1977);

porting to represent all the UGDP documents that had come into the FDA's possession during the course of the UGDP audit. Acknowledging in advance that the documents were "not as informative as you might like,"¹⁹ the FDA stated that instead of having the raw data copied and forwarded to the agency for audit, it had performed the audit by going out to the Coordinating Center, reviewing the raw data on-site, selecting portions of the data for abstracting, and even smaller portions for copying and transmittal back to the FDA. All that the FDA provided petitioners in fulfillment of its pledge at oral argument were the few UGDP documents which had been selected for copying and physical transfer to the FDA.

Suspension of Phenformin Pending FOIA Appeal

On July 25, 1977, while the FOIA appeal was pending, HEW suspended the New Drug Application for phenformin, an oral hypoglycemic medication and one of the drugs studied by the UGDP, as an "imminent hazard to public health."²⁰ This was the first time the provisions of 21 U.S.C. § 355(e) had ever been invoked in this manner. In his Order suspending the drug, Secretary Califano stated that HEW placed a primary reliance on the UGDP data and the FDA's endorsement of the study.²¹

Letter from Mark A. Elengold of FDA's Information Office to Neil L. Chayet (May 20, 1977). The text of these letters is set out in App. Br. 19a to 24a.

¹⁹ Letter from J. Richard Crout, M.D., Director of FDA Bureau of Drugs to Neil L. Chayet (February 9, 1977), App. Br. 19a.

²⁰ In re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval (July 25, 1977).

²¹ *Id.* at 38.

The full administrative hearing on the suspension order reached the oral testimony phase on October 4, 1977. Prior to that time all participants at the hearing, including FDA, had executed a statement required by regulation (21 C.F.R. § 12.85) that they had submitted for the administrative record all data in their files relevant to the case and, beyond that, all data upon which they relied for purposes of the hearing. Neither the UGDP raw data nor the audit findings were included in FDA's submission. Only a copy of the published UGDP reports was submitted.

Petitioners, who participated at the phenformin hearing, objected to FDA's omission of the UGDP raw data, and the Administrative Law Judge ordered FDA to come forward with all UGDP data in their possession.²² On October 6, 1977, the next to the last day of the phenformin hearings, FDA presented the participants with several thousand pages of data gained through the FDA audit of the UGDP. FDA acknowledged that these materials did not include all raw data reviewed by FDA personnel at the Coordinating Center, but simply those limited portions of the raw data that had been copied, abstracted, or directly transferred to government premises. FDA further stated that the audit report was in its final draft stages but not ready for submission.

On February 6, 1978, the Administrative Law Judge issued his decision upholding the HEW suspension

²² In the Matter of the Proposal to Withdraw Approval of the New Drug Application for Phenformin Hydrochloride (FDA Docket No. 77N-0150), Hearing Transcript at 143 (October 5, 1977).

order. In so doing, the Judge acknowledged considerable problems with the FDA's reliance on the UGDP:

Although certain underlying [UGDP] data was made available during the hearing, it was admittedly incomplete. The lack of availability of underlying data casts considerable doubt on the reliability of the UGDP conclusions from an evidentiary standpoint. To the extent such data was not made available, the UGDP conclusions cannot be considered as substantiated on this record.²³

Nonetheless, the Judge proceeded over petitioners' objections to permit the UGDP to be used in support of the agency's position on phenformin. The stated reason for this action was that no participant had provided the Judge with a "specific analysis" of the "precise extent" to which the UGDP data were faulty.²⁴ Since such an analysis would have required review of all of the raw data, petitioners were confronted with a "Catch-22" result.²⁵

²³ In the Matter of the Proposal to Withdraw Approval of the New Drug Applications for Phenformin Hydrochloride (FDA Docket No. 77N-0150), Initial Decision of Administrative Law Judge Daniel J. Davidson at 7 (February 6, 1978).

²⁴ *Id.*

²⁵ It should be pointed out that even on the basis of the very limited portions of the raw data turned over by the FDA on the last day of the phenformin hearings, CCD was able to prepare an analysis which cast serious doubt on the validity of the study, particularly as applied to the suspension action. This analysis was submitted for the administrative record. However, it was not until the FDA released its UGDP audit report more than a year later, that the FDA first acknowledged the accuracy of CCD's analysis.

We agree with CCD that this patient probably should not have been a candidate for phenformin therapy . . . *However it is not the purpose of this audit to pass judgment on the propriety of details of the UGDP study but rather to assess its validity.*

Decisions of Court of Appeals

On July 25, 1978, the Court of Appeals issued its Opinion that the UGDP raw data were not "agency records" under the FOIA. Speaking for the majority, Judge Leventhal defined the test of "agency records" in terms of whether an agency had "created" or "obtained" those records in the course of doing its work (A. 232). Further interpreting the test, Judge Leventhal stated that where records are created by a private entity, the applicability of FOIA will turn on whether the government is involved in the "core planning or execution of the program" (A. 232).

In his dissenting opinion, Judge Bazelon stated that the UGDP data were "agency records" under the FOIA, since the government had been "significantly involved" in the study in terms of funding, access to the raw data, and reliance on the study as the basis for regulatory action.

On July 25, 1978, petitioners filed a Motion for Rehearing and Suggestion for Rehearing En Banc, citing in particular the extensive government involvement in the core planning and execution of the UGDP which met the test established by the majority opinion (A. 261). The motion was denied on October 17, 1978, with

The Food and Drug Administration Audit of the University Group Diabetes Project, Appendix K at 4 (October 16, 1978) (emphasis supplied).

Since the patient referred to was one of only three UGDP-reported cases of adverse reaction to phenformin and the *only* phenformin mortality, the above concession by the FDA undermined the entire basis for its suspension action of one year before, at least insofar as the action was based on the UGDP study.

Judge Bazelon voting for rehearing on the basis of petitioners'

strong case that, from the inception of the study, the government involvement in planning and execution has been pervasive (A. 259).

Developments Since the Court of Appeals Decisions

Nearly three years after the FDA audit was announced, the FDA published in the Federal Register of November 14, 1978 a notice of public availability of its audit report, 43 Fed. Reg. 52732 (1978). The report acknowledged "errors and discrepancies" between the UGDP raw data and the published reports but found that none appeared to be of "sufficient frequency or magnitude to invalidate" UGDP findings.²⁶ At the same time, FDA reissued its 1975 proposed regulations relabeling the oral hypoglycemic drugs, 40 Fed. Reg. 28587 (1975).

By FDA design, the scope of the audit was limited and excluded review of the clinical course and judgments critical to determining the validity of the raw data. Publication of the restricted FDA audit, far from ending the UGDP controversy, predictably led to its further escalation.

- One of the UGDP's own investigators, Dr. Charles Kilo, termed the UGDP a "Medical Watergate"²⁷ and urged the FDA not to take further action based on the UGDP. His conclusion was based on his own analysis of portions of the UGDP raw data, which had been made avail-

²⁶ The Food and Drug Administration Audit of the University Group Diabetes Project, at 2 (October 16, 1978).

²⁷ "Sugar Coated Audit," Barron's (January 15, 1979) at 9.

able to him by some of the clinical centers after the Coordinating Center had denied him access to the complete raw data.

- A former Commissioner of the FDA, Dr. Charles C. Edwards, admitted that his agency had erred when it adopted the UGDP report in 1970 and called for HEW, FDA, and other government agencies to recognize that they had assumed a "partisan position" in the matter and that the principle of checks and balances required them not to proceed as "participant, policeman, prosecutor, judge, jury, and Supreme Court."²⁸
- *Science*, the prestigious voice of the American Association for the Advancement of Science, published an updated analysis of the UGDP controversy, indicating serious scientific opinion moving away from continued endorsement of the study.²⁹
- The American Medical Association requested its Council on Scientific Affairs to reassess its former position in support of the UGDP in light of recent developments.³⁰
- The American Diabetes Association called for total "reappraisal" of the UGDP data, suggesting that UGDP published reports required re-study and modification because prior reviews of

²⁸ Interview with Charles C. Edwards, M.D., Medical Tribune (January 17, 1979) at 6.

²⁹ See note 6 *supra*.

³⁰ Telegram from American Medical Association Executive Vice-President James H. Sammons, M.D., to HEW Secretary Joseph Califano, the National Institutes of Health, The American College of Physicians, the American Association of Family Practice, the American Society of Internal Medicine, and the U.S. Surgeon General (February 2, 1979).

the UGDP raw data had been inadequate. While questioning the logistical feasibility of performing a new review, the ADA stated as follows:

The unique nature and size of the UGDP study, its multi-centered base, the time now elapsed from the inception of the study, and the previously proposed governmental decisions concerning the nature of professional advice that physicians should give their diabetic patients suggest . . . that access to and review of data from the twelve centers of the UGDP should be carried out by ad-hoc review groups.³¹

On the basis of these and thousands of other comments from the public, the FDA announced an extension of time for its proposed relabeling of the oral hypoglycemic drugs, first until March 16, 1979, and then until July 16, 1979.³²

SUMMARY OF ARGUMENT

In the Argument that follows, petitioners demonstrate that the UGDP raw data constitute "agency records" under the FOIA and are subject to disclosure to petitioners and other members of the public. Disclosure is required as a matter of law because the government was significantly involved in the UGDP, through total funding of and core participation in the design, implementation and policy direction of the study. Further, the government had unrestricted rights of access to all of the UGDP raw data by virtue of its contractual and

³¹ American Diabetes Association, "A Statement on the UGDP Controversy" (January 12, 1979) at 4-5.

³² 44 Fed. Reg. 17720 (1979).

regulatory relationship with the UGDP. Having invoked these rights on at least two occasions to sponsor and conduct audits of selective portions of the data, the government asserted control over the data as a whole. Further, the government absorbed the UGDP data into the regulatory process by relying upon the data for purposes of regulatory decision making. Such reliance brought the data squarely within the information base upon which the government took action and the raw data are thereby subject to disclosure as "agency records" under the FOIA.

Accordingly, petitioners respectfully request this Court to reverse the decisions of the Courts below and deem the UGDP raw data "agency records," disclosable under the FOIA.

ARGUMENT

Introduction

This is an unprecedented case. The issue of whether the UGDP raw data, locked in a Maryland bank vault, constitute "agency records" subject to the FOIA cannot be resolved by statutory language, specific legislative history, administrative memoranda relating to intent, or the common law. Rather, this Court must be guided by the general intent of the Congress in enacting the FOIA, case law that only tangentially addresses the instant issue, an understanding of agency resistance to broad implementation of FOIA principles, and common sense.

In order to address properly the dominant issue of this action, its scope must be defined and its impact measured beyond the instant case. A judgment by this Court that the raw data are "agency records" will have

limited impact on the vast array of government sponsored research for several reasons. First, the UGDP study is unique in terms of both its original design and the role the government played in the study once its regulatory implications became apparent. Second, the UGDP is essentially a nonreplicable scientific event spanning many years, many patients, many dollars, and multi-centers.

The uniqueness and non-replicability of the study, coupled with the substantial role the government played in its design, implementation, and monitoring significantly narrow the range of government sponsored research that is affected by this case. Moreover, the government retains the right to define the parameters of "agency records" by virtue of its control of the contractual and regulatory relationship with private research grantees and the regulatory uses it chooses to make of research that it sponsors.

For these reasons, petitioners submit that public access to the raw data simply does not have the "awesome implications" postulated in the majority opinion below (A. 234). Given the broad remedial purposes of the FOIA, the implications would be greater by far if the relief sought here were denied.

The purpose of the FOIA is to permit public scrutiny of agency actions by affording broad public access to "agency records." See, e.g., Davis, *The Information Act: A Preliminary Analysis*, 34 U. Chi. L. Rev. 761 (1967). Nowhere in the Act or its legislative history is the concept of "agency records" defined. Twelve years of judicial experience have, for the most part, focused on the nine exemptions to the Act, leaving the definition of "agency records" largely unexplored. This

is surprising since the threshold question of "agency records" is basic to every FOIA inquiry.

From the relatively few cases that have dealt with "agency records," several propositions of law emerge. First, the situs of particular records in question, whether within or without agency confines, is not dispositive. See *Goland & Skidmore v. CIA*, No. 76-1800 (D.C. Cir. May 23, 1978) (Congressional hearing transcript in the possession of an agency held not to be an "agency record" for purposes of FOIA) and see other cases cited in Dissenting Opinion below (A. 241, fn. 3); See also *Tax Reform Research Group v. IRS*, 419 F. Supp. 415 (D.D.C. 1976) (records generated outside of agency and not within agency possession at time of FOIA request are "agency records" under FOIA).

Second, documents need not be prepared within the physical confines of an agency to be "agency records" *Washington Research Project, Inc. v. DHEW*, 504 F.2d 238 (D.C. Cir. 1974) (site visit reports prepared by outside consultants appointed to assist NIH in making grant determinations are "agency records"); *Wu v. National Endowment for Humanities*, 460 F.2d 1030, (5th Cir. 1972) *cert. denied* 410 U.S. 926, (memoranda and other work products prepared by outside consultant to recommend course of agency action on grant application are "agency records").

Third, traditional common law property inquiries into title and custody, whether the records are publicly or privately owned, are similarly not dispositive. See *Ciba-Geigy Corp. v. Mathews*, 428 F.Supp. 523 (S.D. N.Y. 1977) (UGDP raw data would be "agency records" if subject to substantial government use or control, whether or not owned by the government).

While the courts have not agreed on a specific test defining "agency records", what consensus exists generally avoids a narrow and technical approach, *cf. Nichols v. United States*, 460 F.2d 671, (10th Cir. 1972) *cert. denied* 409 U.S. 966; Concurring Opinion below (A. 239), in favor of a more functional approach based upon all of the circumstances of the given case.³³

The importance of this functional approach is reinforced by a recent Report to the President by the Domestic Council Committee on the Right of Privacy. The Report documents the inappropriateness of applying traditional common law property analyses to new developments in information sharing and use.³⁴ What emerges is a conceptualization of "agency records", not in traditional terms of ownership or possession, but rather in terms of exploring information use relation-

³³ Compare "significant Government involvement with the records" test, *Ciba-Geigy Corp. v. Mathews* at 529; test of Government involvement in "the core planning or execution of the program", Maj. Op., (A. 232 note 19); test of "significant degree of federal involvement with the records", Dissent (A. 245).

³⁴ "Property concepts have been central to legal theory and social and economic activity in our society. But concepts of property were formulated to deal with tangibles . . . When information, ways of dealing with information, or information products are treated as property, issues arise which differ from those resulting from the application of property theories to tangible matter. . . . Some of the characteristics of information make definition and enforcement of property rights difficult.

- Information can be infinitely shared. It can be sold, exchanged, or given away, and yet retained by the transferor.
- Information is transferred via a marker or carrier (e.g. books, magnetic tape, microfilm), but the value of the information is independent of the value of the marker."

Report to the President of the United States by the Domestic Council Committee on the Right of Privacy, NATIONAL INFORMATION POLICY, 61-62 (1976).

ships between government and outside parties on a case by case basis. Involved in the instant case is not a transfer of title but rather the need for a transfer of information. The arguments below demonstrate why the UGDP raw data must be deemed "agency records" and thereby disclosable under the FOIA.

1. RAW DATA DERIVED FROM A SCIENTIFIC STUDY FUNDED ENTIRELY BY A GOVERNMENT AGENCY WHICH WAS SIGNIFICANTLY INVOLVED IN THE STUDY'S PLANNING, IMPLEMENTATION, AND MONITORING, CONSTITUTE "AGENCY RECORDS" DISCLOSEABLE UNDER THE FOIA.

The UGDP was funded entirely by the National Institutes of Health (hereinafter NIH) and was subject to the regulations established by NIH and its parent agency, the Public Health Service (PHS), to govern NIH-sponsored extramural research. The fundamental principle of the extramural regulations is partnership; a partnership between NIH as the granting institution and the network of grantee institutions and scientists.³⁵

PHS requires initial review and critiques of all extramural research protocols by PHS staff, outside consultants, and/or advisory groups. 42 C.F.R. § 52.13. Once approved, the research is monitored by on-site visits and review of the grantee's annual progress and financial reports. 45 C.F.R. §§ 74.82, 74.83. Major programmatic or budgetary changes require prior PHS approval. 42 C.F.R. § 52.20. The grantee's use of inventions, discoveries, or other materials resulting from

³⁵ Public Health Service Grants Policy Statement, DHEW Publication No. (OS) 74-50,000, July 1, 1974.

such research are subject to the approval of PHS under such terms and conditions as may be imposed. 42 C.F.R. §§ 52.22, 52.23. The government retains an unrestricted license to use the products of the scientific endeavor. 45 C.F.R. § 8.1.

PHS regulations also establish broad rights of government access to grantee records in order to promote grantee accountability. PHS officials are authorized access to:

any books, documents, papers, and records of the grantee which [are] determined . . . pertinent to a . . . grant for the purpose of making *audit, examinations, excerpts, and transcripts*. 45 C.F.R. § 74.23 (a) (emphasis supplied).

Where records located outside the agency are determined to have long-term retention value, they can be ordered physically transferred to PHS custody. 45 C.F.R. § 74.20(b). The public at large has its own rights of access to grantee records, which can be restricted only in special and limited circumstances. 45 C.F.R. § 74.24.

Cumulatively, these regulations define the fundamental policy of partnership:

the public interest will . . . be best served if inventive advances resulting [from research grants] are made freely available to the Government, to science, to industry, and to the general public. 45 C.F.R. § 8.0.

And again:

It is the general policy of the Department that the results of Department research should be made widely, promptly, and freely available to other research workers and the public. 45 C.F.R. § 6.1.

Through regulatory implementation of the partnership principle, NIH has sought to achieve two important goals relevant to this case. First, it has created a mechanism assuring grantee accountability, both fiscal and programmatic. Second, it has retained virtually unrestricted rights of access to grantee records, with or without demonstration of cause.

As applied to this case, the specific regulations defining the NIH-grantee partnership are not constitutionally mandated. NIH could choose to establish a different type of partnership structure providing less (or more) grantee accountability or autonomy. Similarly, would-be grantees could decide that the benefits of NIH funding are outweighed by the costs of NIH control and therefore decline involvement in the extramural program. But where, as here, the UGDP voluntarily applied for and received NIH funding, it is and was at all times subject to the full panoply of NIH regulation and authority. *North Carolina v. Califano*, 445 F.Supp. 532 (E.D.N.C. 1977), *aff'd. mem.*, 435 U.S. 962 (1978). This authority included virtually unrestricted rights of government access to research records.³⁶

In addition to the regulations of NIH and PHS, the UGDP was also subject to direct regulation by the FDA. The UGDP applied for and received two Investigational New Drug exemptions (INDs) from the FDA, one of which was specifically for "administra-

³⁶ The majority's concerns about federalism must be viewed in light of the principle recently reconfirmed in *North Carolina v. Califano* that

Without question, Congress in making grants . . . to the states should be vitally concerned with the efficient use of the funds it appropriates for that purpose . . . [and] . . . [it] . . . certainly had the power to attach to its grants conditions designed to accomplish that end. *North Carolina v. Califano* at 534.

tive record-keeping purposes" (A. 112). Having issued INDs, FDA had unrestricted rights of access to UGDP records for purposes of "inspection and copying" under its own regulations. 21 C.F.R. § 312.1.

While now acknowledging its comprehensive authority over HEW-sponsored research, the government has sought to characterize such authority as one rarely invoked. Great emphasis has been placed on typical grantor-grantee relationships where the government simply funds research and the private grantee conducts research with a minimum of government direction and involvement.³⁷ As the Director of NIAMDD has stated:

. . . [I]t is *not the normal practice* of NIH . . . to require grantees to submit their raw data for

³⁷ This argument of the government was implicitly adopted by the Majority when it established its "core participation" test citing *U.S. v. Orleans*, 425 U.S. 807 (1976). That case raised the question of whether, by virtue of receiving federal funds, an otherwise private, non-profit corporation became a "federal agency" for purposes of the Federal Tort Claims Act. The Court found that, absent detailed federal control of the grantee's activities, the grantee could not be deemed a federal agency under the Act. The holding in *Orleans* is in accord with the nexus test established by this Court in *Jackson v. Metropolitan Edison*, 419 U.S. 345 (1974), defining "state action" under the 14th Amendment. However, since the instant action does not raise the question of whether a grantee is a "federal agency" by virtue of its receipt of federal funds, it should not be evaluated on the basis of whether the government assumed control of grantee activities. *Orleans* and *Jackson* are not relevant to the inquiry here, since it is not the grantee's activities that are at issue (as they are in tort or state action litigation), but rather the records generated from such activities for purposes of determining "agency records" *vel non* under the FOIA. Petitioners state, however, that even under the "core participation" test, the UGDP raw data are "agency records" in view of the special relationship developed between NIH, FDA and the UGDP.

review and, in fact, submission of raw data to the Institute is *extremely rare*. Management of the day-to-day operations of grant-supported activities is the responsibility of the grantee. Supervision of the grantee's funded activities by this Institute is *generally limited* to review of periodic reports submitted by the grantee. (A. 147) (emphasis supplied).

Notwithstanding the accuracy of Dr. Whedon's characterization of the typical NIH-grantee relationship, the relationship between NIH and the UGDP was unique from inception through completion. Unlike most extramural research that is designed and developed privately and then submitted for federal approval and funding, UGDP design and development was itself the result of a substantial federal investment. In 1959, and again in 1960, NIAMDD awarded planning grants to six investigators to formulate a specific protocol for conducting the UGDP. This process was supported additionally by NIH's own in-house services.³⁸ While management of the day-to-day operations of grant activities are generally the grantee's responsibility, from the outset NIH assured itself a direct role in the conduct of the study through assignment of an employee as liaison officer to the study with *ex officio* membership on the UGDP Executive Committee.³⁹

Again in contrast to its general practice, NIH evaluated UGDP renewal grant applications not only by

³⁸ For example, G. Donald Whedon, M.D., Director of NIAMDD, served as a statistical consultant to the UGDP. University Group Diabetes Program Address Directory (July 1969).

³⁹ From 1959 to 1970, three different NIH employees were assigned as liaison officers to the UGDP. As members of the Executive Committee, they were responsible for the overall management and conduct of the UGDP.

grantee progress reports but by first-hand observations and recommendations from a Policy Advisory Board. This Board was established as a result of an NIH-imposed condition for grant renewal in 1972 after the study's regulatory implications became apparent. Chaired and directed by Dr. Thomas Chalmers, an NIH employee and Director of the NIH Clinical Center, the Board met at NIH headquarters. It was assigned responsibility for overseeing all UGDP activities, including activities of the Executive Committee, rendering advice on UGDP policy matters, and reporting to NIH on UGDP developments with recommended courses of action.

Finally, and significantly, while NIH's "normal practice" did not entail submission of grantee raw data for review, the UGDP raw data were twice submitted for review for persons acting under NIH sponsorship or direction; first Biometrics, from 1972 to 1974, and then the FDA, from 1975 to 1978. If submission of raw data for outside review was, by Dr. Whedon's own characterization, "not the normal practice" and "extremely rare", then the UGDP was not the normal NIH sponsored study. NIH was significantly and directly involved in the "core" of the UGDP, and UGDP records are therefore "agency records" under the FOIA.

The Majority opinion below expresses the policy concern that, should the raw data be considered "agency records", principles of freedom of science and grantee autonomy would be compromised. Petitioners themselves are physicians and scientists who have received federal grants to support their work and are keenly sensitive to any action, governmental or otherwise, that would compromise such principles.

However, disclosure of the raw data in this case would in no way impact upon grantee autonomy and, instead of infringing upon freedom of science, would serve to advance and fulfill it.⁴⁰

To understand why this is so, one must appreciate that the UGDP raw data, locked in a Maryland bank vault, are a unique scientific resource. UGDP investigators were provided with more than fifteen million federal dollars to conduct this unprecedented twelve-site study. The patient observation phase alone lasted in many cases for over fifteen years. In addition to the logistical problems of attempting replication, the years required to collect comparable data would render such data of no value to contemporary medical and scientific debate concerning the proper treatment of diabetes mellitus.⁴¹

Replication is one of the processes by which science is made accountable. It assures the accuracy of re-

⁴⁰ The principle of grantee autonomy is not at issue in this action. That principle is concerned solely with preventing the Government from controlling legitimate scientific inquiry by requiring science to be conducted by a particular means, or towards a particular end, or with some restriction imposed upon a grantee's right to communicate scientific findings freely and openly to the public. See, e.g., Robertson, "The Scientist's Right to Research: A Constitutional Analysis," 51 CALIF. L.R. 1203 (1978). Grantee autonomy is not infringed or even involved when the issue is the extent to which a federal grantee's product is to be shared under the FOIA with scientific colleagues and other members of the public. See also Mason, "Current Trends in Federal Grant Law—Fiscal Year 1976," 35 FED. BAR 163 (1976).

⁴¹ There are serious questions at this point whether the UGDP could ethically be replicated because of the manner in which the study was conducted; i.e., administering to diabetic and non-diabetic patients fixed doses of insulin, which was contrary to either then-accepted or now-accepted clinical practice of variable dosage administration.

ported findings, the validity of underlying data, and the core integrity of the scientific endeavor.

Scrutiny in science normally means replication. . . . One would expect mathematics to be relatively free from fraud . . . because it is relatively easy for an expert to check the evidence—it is mainly in the published article. For empirical science, the evidence remains behind . . . closed doors . . . and *only summary numbers are presented in publications. If one suspects the evidence supporting a study, the usual procedure is to replicate the work.* Weinstein, "Fraud in Science," 59(4) *Social Science Quarterly*, 639, 645 (1979). (emphasis supplied).

Government sponsored multi-center studies like the UGDP have inherent problems both clinical and ethical:

It has proven very difficult to ensure that all investigators working on a common problem will actually carry out their observations according to common, agreed upon standards. The difficulties become particularly marked when the study involves repeated clinical observations which by their very nature allow the intrusion of a large subjective element.

Finally, there is almost bound to be a higher degree of potential conflict of interest in the collaborative programs than in other parts of NIH operations. . . . The people one turns to for advice on whether or not to enter a certain project area are likely to be the same people who design a possible project, provide opinions on its feasibility or merit, and finally receive the funds to carry it out. Report to the President, "Biomedical Science and its Administration: A Study of NIH" (1965) at 204-205.

Similar charges have been leveled directly at the UGDP.⁴²

Where, as here, a study is not replicable, validation of its findings and determination of its integrity can only be provided by corroboration of existing data. Thus corroboration, like replication, is an essential verification methodology.

For the above reasons, petitioners contend that a voluntary partnership existed between the government and the UGDP based upon comprehensive regulations authorizing unrestricted government access to the UGDP raw data. The above discussion further demonstrates that the government was a core participant in the design, implementation, and monitoring of the UGDP. Disclosure of the UGDP raw data will in no way infringe upon grantee autonomy or the freedom of scientific inquiry. Accordingly, the UGDP raw data are "agency records" under the FOIA.⁴³

⁴² In addition to Dr. Bowen's questioning of respondent Klimt's integrity and the possibility of manipulation of the raw data at the Coordinating Center, (Statement of Angela Bowen, M.D., see note 10 *supra*) respondent Klimt was accused of conflict of interest by Dr. Shirley Weisenfeld, another UGDP investigator, and was asked to resign from the study in 1971. This charge arose out of Klimt's serving as full-time Director of the Office of Scientific Coordination at the FDA while at the same time continuing as Director of Coordinating Center operations. Letter from Dr. Klimt to Dr. Shirley Weisenfeld (December 16, 1970). (App. Br. 16a).

⁴³ For purposes of defining the scope of "agency records," the Government has suggested a difference between research conceived without a "specific regulatory objective in mind" and other types of research with regulatory implications from the outset. (A. 146) See also Maj. Op. below (A. 228). Petitioners submit that the UGDP actually represented a third type of research which, though non-regulatory at outset, became increasingly regulatory as the study progressed, with concomitantly closer Governmental monitor-

2. RAW DATA RESULTING FROM GOVERNMENT-FUNDED RESEARCH WHICH BY CONTRACT AND REGULATION ARE FULLY ACCESSIBLE TO THE GOVERNMENT AND WHICH HAVE IN FACT BEEN PARTIALLY AUDITED BY AND AT THE DIRECTION OF THE GOVERNMENT ARE "AGENCY RECORDS" DISCLOSABLE UNDER THE FOIA.

In prior proceedings below, HEW argued, first, that it had "no authority" to order production of the UGDP raw data, and second, that even if so authorized, it had no obligation to "fetch" the data for FOIA purposes.

For HEW to deny its authority over the raw data is to ignore the plain meaning of its own regulations. These regulations, as discussed above (pp. 28 to 31), grant unrestricted rights of access and control over the data to both NIH and FDA. Therefore, this argument fails.

The "fetch-it" argument is equally defective, since whatever its merits in the abstract, the UGDP raw data have been "fetched" on at least two occasions as a result of HEW directives. Petitioners submit that this fact, by itself, is dispositive in determining the govern-

ing and involvement. It should be pointed out, moreover, that in promulgating its FOIA regulations, the FDA specifically considered and rejected any distinctions between regulatory and nonregulatory research for FOIA purposes.

Upon reconsideration, the [FDA] concludes that it is often not feasible to distinguish between regulatory and nonregulatory testing and research, and that, in any event, there is no sound public policy reason for not disclosing both types of testing and research. 39 Fed. Reg. 44625 (1974).

Thus under the FDA's FOIA regulations, the raw data of FDA-funded research are "agency records" even if the research is conducted by private grantees. 21 C.F.R. § 20.105(d).

ment's authority over and involvement with the data, and that the UGDP raw data are therefore "agency records" under the FOIA.

The first outside review of the data resulted directly from an NIH contract which "urged" Biometrics to "utilize all resources necessary" to assess the UGDP statistics "in-depth" and report back to NIH.⁴⁴ On the basis of its review, including its direct access to the raw data, Biometrics prepared a Report which concluded with "moderately strong" support of the UGDP study.⁴⁵

HEW sought to make much of the fact that, while the raw data were reviewed by an HEW contractor for purposes of rendering advice to the agency, the data still had not been directly reviewed by HEW itself. According to this argument, HEW's rights of access and control over the data remained "inchoate" and therefore the UGDP raw data were not "agency records". Brief of Federal Appellees, U.S. Circuit Court of Appeals, at 34.

Petitioners contend that this argument lacks merit, since there is no intent gleaned in either the FOIA or its underlying principles of broad disclosure to allow common law agency distinctions to dictate the scope of "agency records". For the government to suggest that data utilized by a government contractor in preparation of a final report to the government are not disclosable under the FOIA is erroneous.⁴⁶

⁴⁴ Biometric Report, at 585.

⁴⁵ Biometric Report, at 599.

⁴⁶ See, e.g., 21 C.F.R. § 20.105(d) which requires FOIA access to all raw data and other working materials of an FDA research contractor at the time the final contract report is disclosed. Addi-

Even assuming, *arguendo*, that the definition of "agency records" turns on the government's direct review of the raw data, the fact here is that the government directly reviewed the data by conducting an FDA audit. The audit team, composed of physicians, statisticians, and investigators from FDA staff, acted under designation by NIH

to conduct [an] audit and *exercise all authority* granted to NIAMDD under 45 CFR Part 74 (App. Br. 18a) (emphasis supplied).

This authority was exercised at several different locations, including the Coordinating Center, at least one of the clinical centers, and at FDA offices. A variety of different methods were chosen for conducting the audit, including direct copying, transcribing, and abstracting of forms, oral and written communications, and telephone and computer link-ups. The net result is that the government exercised its authority to audit all of the raw data.

Petitioners submit that, having been subjected to the full auditing authority of the government, the UGDP raw data are "agency records" for purposes of the FOIA. The specifics of where the government decided to perform this audit, whether at the FDA or at the Coordinating Center or at some alternative site, are not

tionally, it should be noted that Biometrics functioned as a group "established or utilized by one or more agencies in the interest of obtaining advice" (5 U.S.C. App. I § 3(2)) and was therefore an advisory committee under the Federal Advisory Committee Act. All "documents which were made available to or prepared for" the Biometric Committee are available to the public (5 U.S.C. App. I § 10(b)). Under this rationale, all of the UGDP data which were retrieved from the Coordinating Center by Biometrics, if not the entire data base made available to them, were public records fully subject to FOIA as early as February, 1975. (See also FDA regulations governing use of advisory committees, 21 C.F.R. § 14.75(8)).

relevant for purposes of the FOIA since the government had the authority to inspect the data at whatever location it wished. Similarly irrelevant are the mechanics of how it chose to perform the audit since, again, it had the right to perform the audit in whatever manner it chose.

The FDA's decision to perform the audit in a partial and selective manner is not relevant to the issue of whether the data are "agency records" under the FOIA. The entire fabric of the Act is to encourage broad disclosure by government agencies in order to minimize the possibility of "secret law."⁴⁷ When only a portion of an otherwise FOIA-exempt memorandum was disclosed by the Maritime Subsidy Board in the context of regulatory action, the Court ordered production of the entire memorandum for public inspection under the FOIA. *American Mail Line, Ltd. et al. v. Gullick*, 411 F.2d 66, 73 (D.C. Cir. 1969). Similarly, the FDA's FOIA regulations provide that a record otherwise exempt from disclosure is *fully* available to the public under the FOIA to the extent that portions thereof are publicly disclosed. 21 C.F.R. § 20.81(a). The FOIA's basic purpose is

to protect the people's right to obtain information about their government, to know what their government is doing and to obtain information about government activities and policies and to *remedy the mischief of arbitrary and self-serving withholding* . . . Note, A Review Of The Fourth Exemption of the Freedom of Information Act, 9 Akron L. Rev. 673, 694 (1976), quoted in *Westinghouse*

⁴⁷ In enacting FOIA, "Congress . . . was concerned with the dilemma in which the public finds itself when forced to litigate with agencies on the basis of secret laws or incomplete information." *Weisberg v. U.S. Dep't of Justice*, 489 F.2d 1195, 1199 (D.C. Cir. 1973).

Electric Corp. v. Schlesinger, 542 F.2d 1190, 1210 (4th Cir. 1976) (emphasis supplied).

Here, where an HEW agency has performed an audit of an HEW sponsored and endorsed study, relied upon for HEW regulatory activity, the FOIA plays an essential role in minimizing the potential agency mischief of "arbitrary and self-serving withholding."

To allow an agency to define the metes and bounds of "agency records" by choosing whether, where, and how to exercise control over records is to invite FOIA gamesmanship. The early interaction between the FDA and the Coordinating Center demonstrates their awareness of the FOIA implications of the audit.⁴⁸ There is considerable evidence to suggest that decisions about the scope, nature, and location of the audit were directly influenced by the desire to limit the agency's FOIA file (see 53, *infra*). Indeed, HEW's conscious use of "data havens" to shelter documents from the FOIA is specifically discussed in the Report of the Domestic Council Committee on the Right of Privacy, a committee of which HEW is a member.⁴⁹

⁴⁸ Shortly after issuance of the District Court opinion below, respondent Klimt contacted the FDA to determine whether it was still necessary for the audit to proceed: "[I] know the time commitments of [FDA] staff are strained, and possibly the most favorable verdict of the District Court of Columbia may change the situation somewhat." Letter from Christian R. Klimt to J. Richard Crout, March 1, 1976.

⁴⁹ "Another issue that has emerged from implementation efforts concerns the scope of the Freedom of Information Act. Because the Congress and its offices (such as the General Accounting Office and the Library of Congress), the States, and the private sector including Federal contractors, are not covered by the Act, agencies sometimes attempt to take information that would normally belong in their own files and maintain the material in these 'data havens.'"

In enacting the FOIA, Congress intended "to pierce the veil of administrative secrecy" and to ensure that documents were not shielded from public disclosure by "unwilling official hands." *Department of the Air Force v. Rose*, 425 U.S. 352, 361 (1976).

Before 1976, the Administrative Procedure Act contained a Public Information section full of loopholes which allow[ed] agencies to deny legitimate information to the public: When Congress acted to close these loopholes, it clearly intended to avoid creating new ones. *Bristol Myers Company v. F.T.C.*, 424 F.2d, 935, 938 cert. denied 400 U.S. 824 (D.C. Cir. 1970).

Petitioners assert a right to review *all* the UGDP raw data and not just the data selected by the government for release to the public.⁵⁰

For instance, Department of Health, Education and Welfare personnel reported to us that they no longer accept possession of drafts of General Accounting Office audit programs because it cannot shelter the documents from FOIA requests. Instead, HEW personnel inspect the drafts at GAO which is exempt from the FOIA.

"The extent of the 'data haven' problem is not yet clear, but insofar as the Federal Government must meet a disclosure standard that exceeds the policies in other sectors, pressures exist for Federal Agencies to 'hide' information in exempt systems." Report to the President of the United States by the Domestic Council Committee on the Right of Privacy, NATIONAL INFORMATION POLICY 51-52 (1976). (emphasis supplied)

⁵⁰ The principle that an entire record must be available for disclosure whenever any portion thereof is sought to be relied on is familiar in other areas of the law as well. For example, the common law principle of "completeness", as embodied in the Federal Rules of Evidence (Rule 106), states:

When a writing or recorded statement or part thereof is introduced by a party, an adverse party may require him at that time to introduce any other part or any other writing or

3. RAW DATA RESULTING FROM GOVERNMENT FUNDED RESEARCH WHICH HAVE BEEN ABSORBED INTO THE FEDERAL DECISION MAKING PROCESS AND FORM THE BASIS FOR AGENCY REGULATORY ACTION ARE "AGENCY RECORDS" DISCLOSABLE UNDER THE FOIA.

The question addressed by the District of Columbia Court of Appeals of whether the UGDP raw data are "agency records" was determined by the majority solely on the basis of "the study and granting activities . . . of NIAMDD." (A. 228). The majority went even further to suggest that FDA's regulatory actions in response to the UGDP were irrelevant for purposes of the FOIA (A. 228). This was apparently based on the view that to the extent the UGDP formed the basis for agency action and the raw data were not forthcoming, alternative relief could be sought under the Administrative Procedure Act (APA). 5 U.S.C. § 551 *et seq.*

Petitioners disagree and contend that FDA's reliance on the UGDP raw data for regulatory decision making is itself grounds for finding that the data constitute "agency records." Further, when combined with the other indicia of government involvement with the data, (See 28 to 36 *supra.*), this absorption of the raw data into the regulatory process inextricably renders them "agency records."

recorded statement which ought in fairness to be considered contemporaneously with it.

Principles of discovery are analogous:

If only a part of a deposition is offered in evidence by a party, an adverse party may require him to introduce any other part which ought in fairness to be considered with the part introduced and any party may introduce any other parts. F.R.C.P. Rule 32.

Petitioners will demonstrate: a) that the UGDP study in fact formed the basis of extensive FDA regulatory action; b) that FDA reliance on the UGDP study included direct reliance on the UGDP raw data; c) that remedies under the APA are no substitute for the remedies of the FOIA; and d) that to disregard the factors of agency reliance and regulatory action as indicia of "agency records" is to create the serious potential for FOIA evasion and abuse.

a. *FDA Reliance On The UGDP Formed The Basis For Regulatory Action*

Even prior to publication of the UGDP findings in December 1970, the FDA had adopted and promulgated a formal agency position in reliance on the UGDP. In a statement delivered to the Subcommittee on Intergovernmental Relations on June 9, 1970, then Commissioner Charles C. Edwards, M.D. described the early relationship between the FDA and the UGDP as follows:

In 1968 we received an initial verbal communication from the UGDP pointing out that early reports seemed to show an excess mortality in those groups assigned to tolbutamide compared to other groups. At that time the preliminary data had not been completely analyzed . . .

In June 1969 a progress report on tolbutamide was received by the FDA. At a meeting with representatives of UGDP they presented their data and a statistical evaluation. *The FDA presented this material to our Medical Advisory Board who recommended that the FDA review the raw data and continue in close contact with the UGDP.*

However, further data were not forthcoming until March 1970 when we received an advance copy

of the manuscript of the report on this study. This report was reviewed by the FDA and an *ad hoc* expert advisory committee. Despite a number of limitations in the study, the agency and the advisory committee agreed with its stated conclusions . . . As soon as the *ad hoc* expert advisory committee had reached its conclusions, the Food and Drug Administration immediately issued a press release on the subject in which it was emphasized that the oral antidiabetic drugs should be used only for those patients who are not controlled by diet alone, that the dosage should be adjusted to the individual needs of the patient, and that patients taking these drugs should continue on their prescribed regimen until otherwise advised by their physician. The findings of the study and our conclusions were also relayed immediately to the practicing physicians through a telegram sent to all county medical societies with a request that the information be disseminated as rapidly as possible. In addition, we are in the process of mailing directly to every physician in the country a message setting forth the results of this study and our recommendations based on it. The labeling of the products will be changed to require the drug firms involved to institute long-term studies on the use of their products in various types of diabetic patients.⁵¹

Commissioner Edward's statement of nine years ago, before the UGDP controversy erupted full-blown, is significant in several respects. First, it indicates that once the UGDP's preliminary conclusions were made available to the FDA, the FDA actively became involved with the UGDP. The study's conclusions were

⁵¹ Oversight Hearings Before the Subcommittee on Intergovernmental Regulations of the House Committee on Government Operations, 91st Congress, 2nd Session (Statement of Charles C. Edwards, M.D., Commissioner of Food and Drugs, at 15-17).

perceived to have immediate regulatory implications for the FDA. Second, the statement reflects FDA's early awareness of the significance of the raw data and the importance of taking no position until after the data had been reviewed by the agency. Third, the statement confirms the agency's adoption of the UGDP conclusions without having undertaken any review of the underlying raw data.

What followed was a series of FDA regulatory actions based primarily, if not exclusively, on the UGDP:

- *October 30, 1970*—FDA issues a Report on Oral Hypoglycemic Agents, stating that "despite a number of limitations in the study, *the Food and Drug Administration agree(s) with the University Group Diabetes Programs' stated conclusions . . .*" Oral Hypoglycemic Agents: Report of the FDA (October 30, 1970). (Emphasis supplied).
- *May, 1972*—FDA issues a new special warning for diabetes drug labeling which, if implemented, would necessitate many diabetic patients being removed from the oral hypoglycemic medications. "The long term study provided the basis for the labeling." "Final Labeling Approved for Oral Hypoglycemic Drugs," FDA Drug Bulletin (May 1972).
- *July 7, 1975*—FDA again proposes a labeling warning stating:

The judgment of the Commissioner that changes must be made in the labeling of the oral hypoglycemic drugs to reflect the findings of the UGDP study is well known . . .

The warning proposed in this labeling is based primarily on a thorough review and evaluation of the UGDP study . . .

The Commissioner reaffirms his view that the UGDP study is an adequate and well-controlled clinical trial.

. . . The Commissioner believes that the UGDP study is a validly conducted trial . . . 40 Fed. Reg. 28591 (1975).

- *July 25, 1977*—Secretary of HEW suspends phenformin as an imminent hazard, citing the UGDP as the only prospective study of phenformin available and one of four basic sources relied upon. In re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval at 38 (July 25, 1977).
- *October, 1977*—FDA witnesses describe the UGDP as "the best evidence" available in support of FDA's position during phenformin administrative hearing. In the Matter of the Proposal to Withdraw Approval of the New Drug Applications for Phenformin Hydrochloride (FDA Docket No. 77N-0150) Hearing Exhibits B-481 at 8, B-485 at 16, and Hearing Transcript at 341.
- *November 14, 1978*—FDA labeling proposal, the same proposal issued by FDA in 1975, is re-issued by the agency based on the agency's full endorsement of the UGDP. 43 Fed. Reg. 52732 (1978).

As Judge Bazelon stated below, "A clearer affirmation and reliance on the UGDP study is hard to imagine" (A. 252).

b. *FDA Relied Directly On The UGDP Raw Data*

The supposed distinction suggested by the government between the published UGDP results and the underlying data is scientifically without merit. In the

context of scientific research, as recognized by HEW's own regulations, "results" necessarily include not only a study's end-product but its supporting raw data and methodology. 42 C.F.R. § 52.22. By requesting Biometrics to conduct a thorough review of the UGDP, a review that necessarily encompassed the raw data, NIH itself recognized the meaningless nature of this distinction. Lingering reliance upon such a distinction ended when the FDA itself audited the raw data.

Recent regulatory actions taken by the FDA and HEW have been based specifically on the raw data and not just on published conclusions. When the FDA resumed proposed relabeling of oral hypoglycemic drugs four months after release of the final Biometrics Report, 40 Fed. Reg. 28587 (1975), the FDA explicitly recognized the "intense criticism" to which the UGDP conclusions had been subjected and the "wide-spread belief . . . among many physicians that the UGDP study was somehow flawed in terms of its design and execution," *Id.*, at 28588. Accordingly, it "decided to postpone implementation of the warning until [the Biometrics Report] was published." *Id.*, at 28589. After Biometrics conducted "extensive new analyses of the UGDP data taking into account the effect of various baseline variables and cardiovascular risk factors" *Id.*, at 28590, the FDA "accepted" Biometrics' opinion that the findings of increased cardiovascular mortality could not "reasonably be attributed to scientific shortcomings in the study." *Id.*, at 28591.

Under these circumstances, a clear warning is necessary even though a residual uncertainty over the correctness of the study may be present. *Id.*, at 28591.

Similarly, when HEW ordered suspension of the marketing of phenformin in July 1977 based in part on the UGDP, the Order cited the FDA's own analysis of the study:

The FDA, which is experienced in interpreting and analyzing incidence figures for adverse reactions, has examined [the UGDP] statistics and concluded that the incidence figures are scientifically valid. In Re: New Drug Applications for Phenformin, Order of the Secretary Suspending Approval at 11 (July 25, 1977).

Finally, in November 1978, the FDA reissued in proposal form, the relabeling regulations proposed in July 1975. This latest action was based explicitly upon the FDA's audit of the raw data.

[W]hile there are certain errors and discrepancies between the data file on the UGDP study and the published reports, none of these appears of sufficient frequency or magnitude to invalidate the finding that cardiovascular mortality was higher in the [oral hypoglycemic] groups. . . . FDA Audit of the University Group Diabetes Project at 2 (October 16, 1978).

Therefore, by government admission, the UGDP raw data, as well as the published conclusions, have been relied upon directly by HEW and have thereby been "absorbed into the federal decision-making process." Dissenting Opinion below (A. 255). As such, they are "agency records" under the FOIA. See *SDC Development Corporation v. Mathews*, 542 F.2d 1116 (9th Cir. 1976) (test of "agency records" is whether they reflect the agency's decision-making functions); *Tax Reform Research Group v. IRS*, 419 F. Supp. 415 (D.D.C. 1976) (documents relied on by agency for pur-

poses of regulatory action but no longer in agency possession are "agency records" in order to allow the public to know the full basis for agency decisions).

c. Remedies Under The APA Are No Substitute For Remedies Under The FOIA.

Petitioners claim that the raw data are "agency records" under the FOIA because they have been absorbed into, and relied upon by, the federal decision making process. Petitioners do not claim any special entitlement to the raw data by virtue of their status as an interested party in related regulatory proceedings. Petitioners recognize that their right to obtain information under the FOIA is "to be measured by the right of the public to obtain the same information". *Nix v. United States*, 572 F.2d 998 (4th Cir. 1978).

But if petitioners' rights to the raw data under the FOIA are not enhanced by their needs as litigants, neither should they in any way be diminished for this reason. While the Majority below has recognized this point in theory, its denial of FOIA relief relies, to a considerable extent, on the availability of alternative remedies to petitioners. Judge MacKinnon's Concurring Opinion suggests that no harm to the public would result from the denial of FOIA access to the UGDP raw data because "they may be subpoenaed by interested parties" (A. 239). Judge Leventhal's opinion for the Majority refers petitioners to remedies available under the APA as a means of challenging agency action taken without disclosure of the data. However, these alternative remedies have proven to have multiple and serious limitations, both procedural and substantive.

Procedurally, petitioners' standing as a party in UGDP regulatory proceedings has been strenuously contested by the FDA, most notably at the hearings at the FDA in 1977 to review HEW's suspension of phenformin. In that case, the Administrative Law Judge sustained the FDA's objection to petitioners' standing on the basis of an FDA regulation explicitly conferring full-party status only on drug manufacturers. 21 C.F.R. § 314.200(a). As a result, petitioners' role in the hearings was limited to the submission of written statements and briefs, and petitioners had no opportunity to testify or to examine and cross-examine witnesses.

Unlike FOIA proceedings where the burden is on the government to prevent disclosure of information, APA proceedings shift the burden to the private litigant to prove that failure of the government to disclose information is erroneous in fact or in law. 5 U.S.C. § 706(2); See, e.g., *F.C.C. v. National Citizens Committee for Broadcasting, et al.*, 436 U.S. 775, 802-03 (1978). In the phenformin proceedings, petitioners were placed in the untenable position of having to demonstrate error in the FDA's failure to include in the administrative record *all* of the UGDP raw data without being able to demonstrate what the inclusion of such data might have proven.⁵²

Alternative administrative and judicial remedies have proven for petitioners to be the pursuit of pyrrhic process. Nine years after the government first relied on the UGDP as the basis for regulatory action, and after numerous administrative and judicial pro-

⁵² See footnote 25 and pages 17 to 19 *supra*.

ceedings in which the UGDP has been challenged,⁵³ the UGDP raw data remain largely secreted from public view. Only by permitting public access to the entire UGDP raw data can the validity of the study be determined. The social risk of misapplying the UGDP has been and remains a generation or more of diabetic patients receiving improper treatment.

⁵³ *Oral Hypoglycemic Labeling*. Petitioners' litigation in the First Circuit Court of Appeals, described at p. 10 *supra*, resulted in a remand to the FDA with a judicial prayer for discussion and resolution of the UGDP controversy. FDA proceeded to revoke the regulation requiring fair balance in UGDP labeling relied upon by petitioners. 40 Fed. Reg. 28582 (1975). Petitioners, therefore, returned to Court in *Bradley et al. v. Califano et al.*, No. 76-401-M (D. Mass.) on the relabeling issue. Despite the continuing harm which has resulted from the FDA position on the labeling, the court challenge must await final FDA action on the labeling proposal before a complete administrative record is available.

Phenformin. Petitioners challenged the HEW suspension of phenformin in the United States District Court for the District of Columbia (*Forsham et al. v. Califano*, No. 77-1478). The District Court denied petitioners' motion for a preliminary injunction on October 21, 1977, which denial was appealed to the Court of Appeals (No. 77-2071). However, on April 10, 1979, the Court of Appeals dismissed the appeal, stating that issues involving the suspension were mooted since the drug had been permanently withdrawn from the market on November 15, 1978 after the administrative hearing process.

Petitioners had also filed, on December 18, 1978, a Petition for Review to the U.S. Court of Appeals for the District of Columbia Circuit (No. 78-2288) contesting the validity of the withdrawal hearing. (*Forsham et al. v. Califano et al.*). A primary issue was again the application of the UGDP study by FDA to support its position at the hearing despite the agency's failure to submit the raw data of the study as required by FDA's prehearing regulations and due process principles generally. Petitioners also challenged the FDA's denial of petitioners' rights actively to participate in the hearing process. This action appealing the hearing was dismissed simultaneously with the appeal on the imminent hazard suspension. The Court of Appeals ruled that petitioners lacked standing to challenge a drug withdrawal under 21 U.S.C. § 355(h).

d. *Restrictive Definitions of "Agency Records" Invite FOIA Abuse.*

To accept the government's restrictive definitions of what constitute "agency records" is to create the potential for agency evasion of the spirit and letter of the FOIA. That such evasion occurs is demonstrated in the instant case.

The FDA audit was announced while petitioners were pursuing FOIA remedies in the District Court below. Thus, both the FDA and the Coordinating Center were aware from inception of the audit of the FOIA implications of their actions.

Petitioners contend that the scope, locations, and nature of the audit were tailored by the government with FOIA considerations in mind:

... Dr. Klimt stated that prior to initiation of any such audit, he would require from us a written statement including what materials we wished to review . . . He requested that we not include in our letter any reference to copying of materials, stating that he had a previous agreement with Dr. Crout that no patient data would be copied and removed from Baltimore to Rockville. He further noted that *if this were done the data involved would be in the possession of the government and would be available under Freedom of Information to Neil Chayet and the Committee for the Care of the Diabetic, an action which had thus far been successfully opposed in court because the data involved were not in the possession of the government.*

Memorandum of Telephone Conversation between Dr. Klimt and Dr. Lisook, FDA Auditor, March 10, 1976, Subject: UGDP Audit by FDA (emphasis supplied).

When respondent Klimt received no assurance from Dr. Lisook as to the scope of the audit, he telephoned Dr. Crout at his home to pursue the matter further:

Dr. Klimt called me at home regarding the upcoming UGDP audit. He wanted to express his concern that Dr. Lisook was intending, as Dr. Klimt understood it, to copy a large number of documents at the UGDP Coordinating Center. Dr. Klimt stated to me that he felt this was not part of his understanding with me during our previous meetings. I indicated to him that, to my memory, this was the first conversation in which we had specifically discussed the point in any depth. I had stated to him previously that we had no intent of copying documents unnecessary to a careful audit—i.e., *we would not use our investigating authority as a mechanism for removing and ultimately making public all the data in his files*—but we did feel that a careful investigation would require the copying of certain material to document our own findings. FDA Memorandum of Telephone Conversation between Dr. Klimt and Dr. Crout, March 18, 1976. Subject: UGDP Audit by FDA (emphasis supplied).

By August, 1976, the government's initial plan for a large-scale audit and extensive copying of the raw data had changed. This change was reflected in correspondence from Dr. Crout to respondent Klimt:

"[W]e no longer visualize copying any volume of documents, but have instead constructed a three page form to be completed in a stepwise manner in Rockville, Baltimore, and if necessary in Boston." Letter from Dr. Crout to respondent Klimt (August 3, 1976).

The practical result of this revised auditing approach became apparent shortly thereafter when it came time for the government to fulfill its pledge at oral argu-

ment to deliver to petitioners all audit data gathered. FDA was the first to acknowledge the serious limitations of the information it provided.

If these documents are not as informative as you might like, it is because most of our audit was performed by abstracting data from UGDP records rather than by making copies of voluminous available records. (App. Br. 19a-20a).

The documents, not surprisingly, were scant, owing to the FDA's self-imposed limitations on the audit. Having had the opportunity to review all of the UGDP raw data for purposes of a thorough audit, the FDA chose to audit only selected portions, to abstract even fewer portions, and to copy and disclose under FOIA only that minute fraction of the UGDP raw data which it had effectively pre-designated for disclosure under the FOIA.⁵⁴

⁵⁴ Further evidence of the manner in which FOIA principles were circumvented or ignored by the FDA came when petitioners attempted to obtain a copy of the audit report prior to its public release. Petitioners' request was denied August 7, 1978 on the grounds that the report was still "investigative in nature" and an "intra-agency memorandum." However, when the final report was publicly released on November 14, 1978, it became apparent from enclosures thereto that FDA had shared earlier drafts of the report with the UGDP Coordinating Center that was the target of the investigation and had even received return comments. Under the FDA's FOIA regulations, neither of the cited exemptions could lawfully be invoked. 21 C.F.R. § 20.64(c) states that an investigatory record disclosed to the subject of an FDA investigation loses its FOIA investigative status and is immediately subject to public disclosure (with exceptions not here relevant). Further, under well settled FOIA principles and FDA regulations (21 C.F.R. § 20.62), any reasonably segregable factual portion of an intra-agency memorandum must be made available

Petitioners contend that selective screening of records by government agencies is violative of the spirit of the FOIA. The FOIA does not contemplate allowing government agencies, by their action or inaction, to restrict intentionally the level of public disclosure of "agency records." To do so would subvert the very essence of the Act—freedom of information to the public.

for public disclosure. If the UGDP Coordinating Center received an advance copy of the factual portion of the draft audit report, then that same portion should have been immediately available at petitioners' request. If the Coordinating Center received more than the factually segregable portion, then for the FDA to have continued to shield the report from disclosure as an intra-agency memorandum is to suggest that the FDA viewed the Coordinating Center as an integral part of internal agency operations.

CONCLUSION

For the foregoing reasons, petitioners respectfully request this Court to reverse the decision of the Court of Appeals for the District of Columbia Circuit and designate the UGDP raw data to be "agency records" under 5 U.S.C. § 552 and therefore subject to disclosure to petitioners and other members of the public.

Respectfully submitted,

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APPENDIX TO BRIEF

(Cited in brief as App. Br.)

**Controversy Over Study of Diabetes Drugs
Continues for Nearly a Decade. 203 Science 986 (1979)**

*A bitter altercation raises major issues facing
clinical scientists and regulatory agencies*

In the next few weeks, the Food and Drug Administration will decide whether all oral anti-diabetes pills should carry warning labels saying they are toxic. And in the near future, the U.S. Supreme Court will decide whether to hear arguments that data from federally funded research should be publicly available. These are issues arising directly from a highly controversial clinical trial—a trial whose results may portend the kinds of difficulties facing supporters of the large crop of clinical trials now being conducted.

The past decade has been a time of bitter debate and accusations within the diabetes community, a time when eminent scientists and physicians became sharply polarized in their opinions on a subject that is, at best, murky. The altercation has been so vituperative that an authority in the field calls it "the most shameful in the history of modern medicine."

The dispute is over the use of oral anti-diabetes drugs. These pills, which lower blood sugar, are popular with doctors and patients and are extremely profitable for the drug companies. But administrators of a major clinical trial, called the University Group Diabetes Project (UGDP), concluded 10 years ago that the drugs are not efficacious and that they are probably toxic as well. This conclusion has since been sharply attacked by one group of physicians and scientists and evangelically promoted by another and the trial itself is the focus of a heated debate.

The tale of the UGDP is more than just the story of an internecine fight. It raises major issues facing clinical scientists and regulatory agencies today. These include the way people behave when their beliefs are challenged by data that are themselves open to challenge, the role of the Food

and Drug Administration (FDA) in taking a stand on controversial issues, the proper treatment of adult-onset diabetics, the public's right to access to data from government-funded studies, and the ultimate value of clinical trials.

The principal figures in the UGDP story are:

- The FDA, which has, by its actions, fanned the fires of the debate. In 1968, the FDA immediately endorsed the UGDP's conclusion that one of the oral anti-diabetes drugs might be toxic and decided to put warning labels on all such drugs. Although court challenges have thus far prevented the agency from going ahead with its requirement for warning labels, it has as yet refused to budge an inch in its position that the labels are necessary.

- The Committee for the Care of the Diabetic (CCD), a group of diabetologists who banded together to contest the FDA's endorsement of the UGDP. The CCD is an impassioned and sometimes strident group which is totally convinced that the UGDP must be discredited.

- Christian Klimt, a biostatistician at the University of Maryland Medical School in Baltimore, who was in charge of the computer coding and analysis of the UGDP results. He has thus far refused to make the study's raw data available and has been accused of manipulating them.

- Angela Bowen, a diabetologist now in private practice in Olympia, Washington, and formerly a principal investigator in the UGDP. Bowen resigned from the study in part because of Klimt's failure to release patient records. She has played a key role in making and publicizing allegations about Klimt.

The UGDP began in 1961 as a major trial to answer questions of vital importance to the country's 2.5 million adult-onset diabetics: What is the value of lowering blood sugar concentrations? and, Are oral anti-diabetes agents a safe and effective way of doing it? These agents, which were in-

troduced in the 1950's, were immediately welcomed by some physicians because they enabled patients to lower their blood sugar level without insulin injections and to avoid the unpopular and often unsuccessful diets prescribed for overweight diabetics. Other physicians questioned the usefulness of the drugs, arguing that it was not at all clear that lowering blood sugar prevents the complications of diabetes and that perhaps overweight patients whose only symptom is elevated blood sugar should just be urged to diet. (Most adult-onset diabetics are overweight and weight loss alone often controls their diabetes.)

The UGDP was to be the world's biggest and best-designed clinical trial. As one of the first large-scale trials ever conducted, it served as a model for the large crop of clinical studies that followed it. When the UGDP began, the general feeling in the scientific community was enthusiasm for its methods and goals. Only later was this enthusiasm to sour and the study to come under attack.

The trial was conducted at 12 university diabetes clinics which recruited a total of 1027 volunteers. The study's design stipulated that the volunteers be adult-onset diabetics with expected lifespans of at least 5 years. The data from the clinics were sent to a coordinating center run by Klimt for analysis.

At the start of the trial, the patients were randomly divided into four groups: those who received a placebo, those who received a fixed dose of insulin, those who received a variable dose of insulin depending on their blood sugar level, and those who received a fixed dose of tolbutamide, an oral anti-diabetic drug. All patients were also given a low-calorie diet. Two years later, phenformin, another oral anti-diabetes drug that had just come on the market, was added to the study.

From 1961 to 1968, UGDP data were gathered and analyzed. At the same time, the oral anti-diabetes drug market

boomed. According to Sidney Wolfe, head of Ralph Nader's health research group, American doctors wrote nearly 17 million prescriptions for the drugs in 1968. More than 50 percent of this market was captured by the Upjohn Company with its tolbutamide sold under the name Orinase. Thus the drug companies, and Upjohn in particular, had a great deal to lose if the anti-diabetes agents did not make a good showing in the clinical trial.

The first shock to the drug companies and to doctors who had been enthusiastically prescribing the oral drugs came in 1970. On 20 May, news was leaked to Wall Street that tolbutamide was to be withdrawn from the UGDP because it did not seem to be efficacious and because there was reason to suspect it caused cardiovascular complications. The reaction was immediate. The price of Upjohn's stock dropped dramatically and doctors switched patients from Orinase to Diabinese, a chemically similar drug made by Pfizer, Inc., or to DBI, the brand name for phenformin then made by Revlon, Inc.

The news from Wall Street puzzled the medical community. After all, tolbutamide was not a new drug and no one had ever before reported that it was toxic. Physicians with diabetic patients began to question the reasons for withdrawing the drug. The tolbutamide patients did not have a higher death rate than those in the other groups—they just had a higher proportion of deaths from cardiovascular causes. Physicians began to ask how the UGDP scientists determined the causes of death, and how the data were analyzed.

Despite these doubts about the validity of the UGDP's conclusions, the FDA, against the advice of its own advisory committee, acted swiftly on the study's results, even though it had not actually seen the UGDP data. Two days after the news about tolbutamide broke on the Dow-Jones ticker, the FDA endorsed the study's conclusions. Three days after that, the agency announced that warning labels

would be put on all oral anti-diabetes drugs. Yet the UGDP results still had neither been published nor presented to a scientific audience.

Three weeks later, the UGDP data were presented and debated at an American Diabetes Association (ADA) meeting at which time the ADA endorsed the study's conclusions. But the results were not to be published for another 6 months.

By the time of the ADA meeting, the debate over the UGDP was focused on the question of whether tolbutamide was toxic. The question intended to be answered by the UGDP—whether control of blood sugar prevents the complications of diabetes—was ignored. It turned out that it was never to be answered because, in most of the patients, blood-sugar levels had been poorly controlled.

As months went by after the news about tolbutamide was reported, questions about the UGDP became louder and more persistent. The FDA stuck by its original decision to put warning labels on the drug.

Soon the simmering discontent of some UGDP investigators about the conduct of the trial and its conclusions came to the surface. In November 1970, Bowen and Robert Reeves, who were UGDP investigators at the Seattle clinic, resigned from the study. They explained that 7 of the 20 UGDP investigators had disagreed with the decision to withdraw tolbutamide. (None of the others resigned.) But Max Miller of Case Western Reserve University, who was chairman of the UGDP, insisted that the decision to withdraw the drug be made to appear unanimous, arguing that otherwise the conclusion would not be accepted by the medical community.

This demand for a false show of unanimity disturbed Bowen and Reeves. They were already suspicious of Klimt because, they said, he had at first denied and then admitted that at the time the study began he had been a paid con-

sultant to U.S. Vitamin Pharmaceutical Corporation, a drug company with a stake in the trial's results, and had continued as a consultant until shortly before his appointment to the FDA. (Phenformin was originally sold by U.S. Vitamin. When tolbutamide was removed from the study, U.S. Vitamin more than quadrupled its sales of phenformin. Then U.S. Vitamin was taken over by Revlon.)

Klimt acknowledged to *Science* that he accepted \$5000 from U.S. Vitamin during the years 1968 to 1970, but expressed astonishment that he could be accused of manipulating data for such a paltry sum.

Also in November of 1970, the CCD was formed by a group of 40 leading diabetologists who had decided to join forces in combating the UGDP. They retained a Boston lawyer named Neil Chayet, who specializes in medical-legal matters, to prevent the FDA from going ahead with its labeling proposal and to gain access to the UGDP's patient records. Chayet has, by a number of legal maneuvers, been able to delay implementation of the labeling requirement for the past 8 years.

The CCD still exists, now numbering about 250 diabetologists. (In contrast, about 2500 physicians are members of the ADA.) Its efforts have played a large role in keeping the UGDP controversy alive—so large a role that the study's supporters commonly preface their remarks about the CCD's arguments by saying that the members of the CCD, and Chayet in particular, are funded by Upjohn. Chayet has denied under oath that Upjohn has ever paid him for any work he did for the CCD.

Within the first year after tolbutamide was withdrawn from the UGDP the scene was set for the continuing dispute. Klimt's integrity was impugned, the CCD was formed, and the study's critics and supporters began to be polarized. But the study was not over. On 17 May 1971, nearly 1 year to the day after the tolbutamide story broke, news was leaked to Wall Street that phenformin too was to be with-

drawn from the study. The UGDP data indicated that the diabetics taking phenformin suffered excess mortality from all causes. When reports of phenformin's imminent demise came over the Dow-Jones ticker, investors rushed to unload their Revlon stock. Revlon took a beating and was forced to stop trading on its stock that day.

When phenformin was withdrawn from the UGDP, the furor over the study and its conclusions knew no bounds. Supporters of the study were becoming increasingly strident. The debate had turned ugly, had turned into a duel in which the weapon of choice was the ad hominem argument. Not only did the critics question Klimt's honesty, but the supporters accused the CCD and other critics of being drug company whores.

At least one critic of the UGDP was even warned that his criticisms and his associations with Upjohn might destroy his academic career. Stanley Schor, who at the time was head of the statistics department at Temple University, was paid by Upjohn to critique the UGDP. He says he quite honestly found faults in the study's design and analysis. Schor had much experience as a consultant, both for industry and for the government. "But this was the first time I ever agreed with a drug company and disagreed with the FDA," he says.

As a result of his role in criticizing the UGDP, Schor was accused of having been bought by Upjohn. He reports that a UGDP administrator said to him, "You have an outstanding scientific reputation. You'd better divorce yourself from these people ([the study's critics] or you'll be finished." Schor says that "a lot of peculiar things" happened after he criticized the study. He subsequently lost his consultantship at the FDA and left Temple University. He now works for Merck Sharp & Dohme.

The UGDP debate was largely limited to the United States. For example, Germany, which was just recovering

from the thalidomide tragedy, was greatly concerned that the drugs might be toxic. Shortly after tolbutamide was withdrawn, a meeting was held in Dusseldorf to discuss the UGDP. After hearing both sides of the debate, the German government decided that no action was required to restrict sales of the drug or warn doctors of its toxicity. The Canadian, British, and Swedish governments also considered the UGDP report no basis for action.

In what turned out to be a futile attempt to answer the persistent angry questions about the UGDP, Robert Q. Marston, who was then director of the NIH, asked that the Biometric Society, which is a professional society of statisticians, appoint a committee to review the UGDP. The committee was appointed in 1971. For 4 years it deliberated, talking to the study's critics, journeying to the coordinating center and various UGDP clinics, and considering other studies that did not support the UGDP's conclusions. Finally it published a report more or less vindicating the UGDP.

The Biometric Society report is a carefully worded document that defended clinical trials in general and answered some questions about the trial but nonetheless failed to satisfy the study's critics.

One of the most troublesome accusations about the UGDP which the Biometric Society committee considered is that the patients given tolbutamide had more risk factors for heart disease than patients given placebos. These are conditions such as high blood pressure and high concentrations of cholesterol in the blood, that increase the likelihood that a person will have heart disease. If these patients were at greater risk to begin with, the increased incidence of cardiovascular deaths in this group could reflect that fact and not the effects of tolbutamide.

In response to this criticism, the committee used a statistical model to decide how many cardiovascular deaths

would be expected in a population with the risk factors of the tolbutamide group. It determined that far fewer deaths would be expected than actually occurred.

A second problem involves data analysis. Critics object to the decision to consider each patient a member of the treatment group to which he was assigned, regardless of whether he adhered to that treatment. They point out that only 26 percent of the UGDP patients faithfully stayed with their originally assigned treatment.

In order to decide whether patients' lack of adherence to their assigned treatments altered the UGDP's results, the Biometric Society committee corrected for lack of adherence by two different statistical methods. Both methods yielded results that confirmed the original conclusion that tolbutamide causes excess cardiovascular deaths.

Still another often-cited criticism of the UGDP's findings is that there may have been some bias in assigning causes of death. As Alvan Feinstein of Yale University points out, many cases of cardiovascular disease are undetected during life and are only discovered at autopsy. Therefore, the more patients that are autopsied, the more likely it is that deaths will be assigned to cardiovascular causes. Fifty percent of the tolbutamide patients that died were autopsied as opposed to only 29 percent of the patients assigned to placebo or insulin. According to Feinstein, the statistical significance of the increased cardiovascular deaths in the tolbutamide group would vanish if only three deaths in each group were reassigned to different causes.

The Biometric Society conceded this point to the critics, saying that "some reservation about the conclusion that oral hypoglycemic agents are toxic must remain."

The Biometric Society report was published in the *Journal of the American Medical Association* along with an editorial by Thomas Chalmers, who is now dean of Mount Sinai Medical School and chairman of the UGDP advisory

committee. (He was then at NIH.) In his editorial, Chalmers estimated that the oral anti-diabetes drugs cause an additional 10,000 to 15,000 deaths each year in the United States. He obtained this estimate by interpreting literally the statistically insignificant trend toward more deaths in the UGDP patients taking tolbutamide. Even though his figures are controversial, Chalmers sticks by them.

While the arguments over the UGDP's design and data analysis were going on, the CCD had stalled the FDA by bringing to court the issue of whether the agency could put its intended warning label on *all* oral anti-diabetes drugs. The committee's argument was that any warning label should present both sides of the issue. It should reflect the controversy over the UGDP and take note of other studies that do not confirm the UGDP's conclusions. Lawyer Chayet contended that the FDA's own fair balance regulation required it to do this. The fair balance regulation was designed to prevent companies from making wild and extravagant claims for their products in package inserts without explaining serious differences of opinion and qualifications when they existed. When the First Circuit Court of Appeals in Boston sent the case back to the FDA asking that the two parties resolve their differences, the FDA modified its fair balance regulation as it applied to the government. Now only the drug companies, and not the FDA, must comply with the regulation.

The FDA tried again to put warning labels on the drugs, holding a hearing in August of 1975 to discuss its proposed labels. At the hearing, two sensational issues were brought up—one legal and the other personal. The legal issue may now be the subject of a Supreme Court case. The personal issue is the subject of an FBI investigation.

The legal question was brought up by Chayet. He attempted, on behalf of the CCD, to obtain the patient records from the UGDP. He explained that the committee's request to look at the raw data had "been shuttled from agency to

agency, ignored or denied." Finally, on 7 August 1975, Chayet received a letter from Theodore Cooper, then Assistant Secretary of HEW. Cooper wrote, "I have made further extensive inquiries of both the National Institutes of Health and the Food and Drug Administration. Neither agency has ever had the raw data in its possession."

Cooper went on to explain that the data apparently belong to Klimt. "I am informed," Cooper wrote, "that the raw data is [sic] now in the form of microfilm and is stored in a Maryland bank vault. . . . While I cannot, therefore, suggest it as a fruitful approach, it would appear that further efforts on your part should be directed to Dr. Klimt."

Chayet has as yet been unable to obtain the data from Klimt. Jerome Cornfield, a statistician at George Washington University who strongly defends the study, says it is only proper that Chayet be denied access to the UGDP data. The CCD, Cornfield explains, only wants to see the data to denigrate the study.

Nonetheless, Klimt explained to *Science* that it has always been his policy that the data should not be released until it had all been analyzed and the analyses published. Now that nearly all the UGDP reports are out, he says, the data are available. The only exceptions are the data pertaining to a monograph on insulin use, which is still being prepared.

Chayet maintains that all the data are not available. The patient records and the forms filled out at the clinics are still sequestered, he says. He says he is taking the issue of whether they should be available to the U.S. Supreme Court, explaining that he believes that in a government-funded study such as the UGDP in which major policy decisions hang on the data, it is inappropriate that neither NIH nor the FDA saw the data. (He says he has some qualms about whether all data from federally funded research should be publicly available, however, because if they are, researchers could be subject to harassment.)

The most inflammatory testimony at the 1975 hearing was Bowen's. She questioned the "personal integrity and scientific honesty" of Klimt, linking his consultantship at U.S. Vitamin to the UGDP's decision to withdraw tolbutamide. She explained that "it became increasingly difficult for investigators to voice legitimate scientific concerns in the semiannual meetings of the UGDP. The entire project sort of began to assume a vendetta-like quality against the manufacturers of tolbutamide."

Bowen's testimony stunned the audience at the FDA hearing and led the FDA to institute an audit of the beleaguered study. The audit results were recently made public. Once again the UGDP was vindicated and once again the critics remain unsatisfied.

At the time the audit was being conducted, FDA officials asked the Inspector General of HEW to look into Bowen's suspicions about Klimt. Chayet explains that, in early 1978, J. Richard Crout, who is head of the FDA's Bureau of Drugs, asked Bowen to come to the FDA and discuss her suspicions. Bowen came, bringing Chayet with her. Following his conversation with Bowen and Chayet, Crout allegedly took steps that resulted in HEW's investigation. (Crout refused to comment on this matter.)

In January 1979, the Inspector General turned the case over to the FBI. William Rhodes of the Baltimore office of the FBI will only say that the statute under which the agency claims jurisdiction is bribery and that it is investigating whether there is any substance to allegations involving Klimt and the UGDP.

Klimt protests that he is innocent and that the FBI investigation is just one more example of the harassment he has been subjected to for the past 8 years. He says he did not even know of the FBI's involvement until *Science* mentioned the matter.

Critics say that their qualms about the sequestered data are increased by some patient records that have recently been released. These records, previously held by Klimt, were turned over to the FDA when the agency was investigating a charge by Wolfe that phenformin is an imminent hazard to human health. As soon as it learned the FDA had these records, the CCD obtained them through a *Freedom of Information Act* request. Then Nathaniel Horowitz, a writer for the *Medical Tribune*, publicized the records in the newspaper. (The *Medical Tribune* had been running a series of articles critical of the UGDP.)

The study's critics were horrified by the evidence of patient mismanagement at the clinics, as revealed in the patient records. For example, some patients with malignant hypertension were untreated, a woman with a preexisting kidney failure and sickle cell anemia was given phenformin (the drug was specifically counter-indicated in her case), and a man with normal blood sugar was given insulin.

In addition to the patient mismanagement, the UGDP records reveal that data were frequently erroneously recorded. This sloppiness in treating patients and recording data is passed off by UGDP supporters who say that a few errors are inevitable in a study the size of the UGDP, and that it is necessary to consider the study as a whole. They point out that, according to the FDA audit, the errors and discrepancies in recording and analyzing data do not alter the UGDP conclusions.

Supporters of the UGDP commonly say that the study's critics are intellectually and emotionally unable to accept the fact that treatment of symptomless adult-onset diabetics does no good. Both Chalmers and Thaddeus Prout, a UGDP administrator from Johns Hopkins University, draw an analogy with a large-scale trial on treatment of high blood pressure that was conducted at about the same time as the UGDP. This study, directed by Edward Freis of the Veteran's Administration Hospital in Washington, D.C., pur-

portedly showed that anti-hypertension drugs prevent deaths and complications of hypertension. But, say Prout and Chalmers, Fries study was no better than the UGDP. Yet his study's results were immediately accepted and Freis won a Lasker Award.

The implication is that there is a widespread tendency in the clinical and research communities to accept findings that drugs are useful and to reject findings that drugs are useless. Freis, on the other hand, says his study is not at all comparable to the UGDP. It answered the original questions it was designed to answer and there was never any doubt about the statistical analysis and significance of its results.

Casting aspersions on the motives of the UGDP critics, however, cannot stem the increasing tide of objections to the study. Recently, Charles Edwards, the former FDA commissioner who accepted the first UGDP results and proposed the warning label, said that he made a mistake in listening to statisticians and not looking at the study's quality control. Edwards, who is now President of Scripps Clinic and Research Foundation, says, "The UGDP was a bad study. Why can't anyone admit that?"

On the other hand, Paul Meier of the University of Chicago, who was a member of the Biometric Society committee, says the UGDP is no worse than any other clinical trial. It's just that no one before had ever seen so much data from a trial. If Meier is correct, what does that say about clinical trials in general? Should their quality control be improved and, if so, how? How much money, time, and resources should be devoted to them?

The FDA has not yet given up its battle to put warning labels on all oral anti-diabetes drugs. It recently proposed a label and planned to accept comments until 15 January 1979. Now, at the request of the ADA, which recently took back its original endorsement of the study's conclusions, the FDA extended its comment period until 15 March. But

the warning section of its proposed label still does not reflect the scientific controversy. Perhaps, as Edwards says, this is an issue in which the FDA should not intervene, should not try to decide in the face of such a dispute whether the UGDP's conclusions are valid.

It has been rumored that the FDA may compromise on its warning label by restricting the warning to tolbutamide. Prout believes such a restriction would be a sellout because it would allow drug companies to profitably market their new anti-diabetes drugs in this country. However, Edwards and others point out that it is hard to justify extending the warning to all anti-diabetes drugs. Even Klimt says he could not scientifically justify such an extension. ("It's not my fault if the FDA over-interpreted our data," he told *Science*.)

Some medical scientists think that the UGDP battle is winding down—that the ADA's change of mind about the study means it is discredited by all but its most strident supporters. They note that now the American Medical Association says it is reassessing its position in support of the UGDP and that the comments received by the FDA on its warning label proposal are overwhelmingly critical of the UGDP. Of course, the debate will not end until the warning label controversy is resolved. This will be the final decision in a fight that, like a bad boxing match, has no sharp punches, no telling blows, no display of finesse—just a lot of clinching, shouting, glancing punches and, finally, desultory pats.

—GINA BARI KOLATA

16a

UNIVERSITY OF MARYLAND

SCHOOL OF MEDICINE
INSTITUTE OF INTERNAL MEDICINE
BALTIMORE, MARYLAND 21201

DIVISION OF EPIDEMIOLOGY AND BIOSTATISTICS

December 16, 1970

Shirley Weisenfeld, M.D.
The Jewish Hospital and Medical
Center of Brooklyn
555 Prospect Place
Brooklyn, New York 11238

Dear Shirley:

Thank you for your letter of December 7 which brings out into the open a question I have discussed previously with Dr. Goldner.

Acceptance of a one-year assignment as Director of the Office of Scientific Coordination of the Food and Drug Administration on my part was purely motivated by the need to assist this important organization in its scientific problems. My position in the FDA has nothing whatsoever to do with the regulatory duties of the organization nor of the review of INDs (investigational drug licenses) and NDAs (marketing permissions for new drugs). Furthermore, I have been specifically excluded from consideration of diabetes and hypolipemic matters by the Director of the Bureau of Drugs. Thus, in no way is there any conflict of interest between my position in the UGDP and my temporary position with the FDA.

As I have told you, my position with the FDA will terminate September 30, 1971. Until this time I am spending twenty percent of my time in Baltimore to take care of my responsibilities with regard to the UGDP and the CDP.

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Like you, Shirley, and many others I have spent a good part of the last ten years helping with the UGDP in its many aspects. I do not think that I ought to withdraw from such a function now nor do I feel it is fair to ask me to jeopardize my scientific involvement. I would therefore have to reject your suggestion that I resign from the UGDP because of the simple appearance and not the fact of a conflict of interest since I am temporarily with the FDA.

Hoping that this letter will have clarified the situation and allayed your fears, I remain as always

Cordially yours,

/s/ CHRISTIAN R. KLIMT
Christian R. Klimt, M.D., Dr. P.H.
Professor and Director

cc: All UGDP Investigators

CRK:meh

18a

DEPARTMENT OF HEALTH, EDUCATION,
AND WELFARE

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

July 13, 1976

Dr. Christian Klimt
Division of Clinical Investigation
School of Medicine
University of Maryland
600 Windhurst Avenue
Baltimore, Maryland 21201

Dear Dr. Klimt:

This letter is to advise you that the Food and Drug Administration, with the authorization of the National Institute of Arthritis, Metabolism, and Digestive Diseases, will conduct an audit of the UGDP study. NIAMDD hereby designates FDA to conduct the audit and exercise all authority granted to NIAMDD under 45 CFR, part 74.

Sincerely yours,

/s/ G. DONALD WHEDON
G. Donald Whedon, M.D.
Director
National Institute of Arthritis,
Metabolism, and Digestive Diseases

cc

Mr. Stuart Pape
Office of the General Counsel
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

19a

DEPARTMENT OF HEALTH, EDUCATION,
AND WELFARE

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

February 9, 1977

In reply refer to F77-1128

Neil L. Chayet
Chayet and Sonnenreich, P.C.
6 Fayette Street
Boston, Massachusetts 02116

Dear Mr. Chayet:

In response to your letter of January 5, 1977 we will release upon receipt of \$39.10 as detailed on the enclosed invoice:

- 1) copies of all documents copied at the UGDP Coordinating Center during the course of our audit,
- 2) a copy of a computer print-out provided us by the Coordinating Center,
- 3) copies of all available baseline electrocardiograms on subjects who died during the course of the UGDP study, and
- 4) copies of pertinent portions of the death record of a subject identified as FDA audit #71 obtained from the UGDP Death Committee records at Massachusetts General Hospital.

The above constitute all the UGDP documents that have come into our possession to date during the course of the UGDP audit. If these documents are not as informative as you might like, it is because most of our audit was per-

formed by abstracting data from UGDP records rather than by making copies of voluminous available records. Data obtained are currently being evaluated. A report of our findings will be available as soon as that evaluation is completed.

Our audit is being conducted by Dr. Alan Lisook of the Bureau of Drugs' Scientific Investigations Staff in conjunction with another physician, statisticians, and personnel of our field staff. It is still in progress. Past visits to the Coordinating Center were made on 8/6 and 8/18 and 9/15 through 10/14/76. A visit was made to Massachusetts General Hospital to review Death Committee records from 9/29 through 10/01/76.

Sincerely yours,

/s/ J. RICHARD CROUT, M.D.
J. Richard Crout, M.D.
Director
Bureau of Drugs

Enclosure

CHAYET AND SONNENREICH, P.C.

ATTORNEYS AT LAW
6 FAYETTE STREET
BOSTON, MASSACHUSETTS 02116

(617) 357-0202

May 5, 1977

Honorable Donald Kennedy, Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Dr. Kennedy:

It has come to our attention that an audit conducted by the Food and Drug Administration regarding the UGDP raw data is now complete. It has further come to our attention that the conclusions of the audit will be made public by the Food and Drug Administration at the early June meeting of the American Diabetes Association.

Please note that on January 5, 1977, request was made on behalf of the Committee for the Care of the Diabetic for all materials gathered by the FDA during the course of the UGDP audit. This request followed specific assurances of the availability of such materials by the Department of Justice speaking on behalf of the Food and Drug Administration during oral argument of the Freedom of Information action brought by the Committee for the Care of the Diabetic (*Forsham v. Califano*, United States Court of Appeals, D.C. Circuit, C.A. 76-1308). On February 9, Dr. Crout responded to our request stating that the materials would be released upon payment of \$39.10 for the costs of reproduction. Despite our having made the requested payment on March 24, 1977 (Check No. 224), we have still not received any of the requested materials.

To release the results of the UGDP audit at a meeting which will receive broad coverage by the lay press and without having made the audit materials available to the Committee for the Care of the Diabetic for *prior* scientific analysis and comment will be to assure a repetition of events of six years ago when diabetic patients first read about the UGDP in the newspapers. Their physicians were unable to explain the meaning of the study, not having seen or had an opportunity to review the data in advance. Such a course of action by the FDA would again be detrimental to the health and welfare of the hundreds of thousands of diabetic patients throughout the United States.

Therefore, on behalf of the Committee for the Care of the Diabetic and pursuant to the Freedom of Information Act, 5 USC § 552 and regulations promulgated thereunder, request is hereby again made for all materials, including the raw data and any abstracts thereof, that were gathered as a result of the UGDP audit. It is requested that such materials be forwarded to the Committee for the Care of the Diabetic as soon as possible.

Very truly yours,

Neil L. Chayet

DEPARTMENT OF HEALTH, EDUCATION,
AND WELFARE

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

May 20, 1977

Our Ref: F77-1,128

Mr. Neil L. Chayet
Chayet and Sonnenreich, P.C.
Attorneys at Law
6 Fayette Street
Boston, MA 02116

Dear Mr. Chayet:

This is in reply to your May 5, 1977 letter to Dr. Kennedy concerning your request for all materials gathered by FDA during the course of the UGDP audit.

Our Accounting Operations Branch states they have no record of receiving your check No. 224 for \$39.10 in payment for this material.

However, we are enclosing the requested records. Please send us a copy of your cancelled check so that we may clear our records.

As you will note, minor deletions of material have been made in the records furnished to you. In the judgment of the Food and Drug Administration the information deleted does not fall within the scope of your request and, in any case, is not required to be disclosed under the Freedom of Information Act. If, however, you do desire to review the deleted material, please make an additional request. If the agency should then deny you this information, you would have the right to appeal such denial to the Department of

Health, Education, and Welfare. Any letter of denial will tell you how to make this appeal.

Incidentally, your sources of information regarding the ADA meeting are incorrect. FDA has no plans to make the conclusions of our audit of the UGDP data public prior to their publication in the Federal Register.

Sincerely yours,

/s/ MARK A. ELEGOLD
Mark A. Elengold
Freedom of Information Officer
Bureau of Drugs (HFD-35)

5 U.S.C. § 552

Title 5

Government Organization and Employees

CHAPTER 5—ADMINISTRATIVE PROCEDURE

Part I—The Agencies Generally

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general

policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967,

and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(4)(A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges for document search and duplication. Documents shall be furnished without charge or at a reduced charge where the agency determines that waiver or reduction of the fee is in the public interest because furnishing the information can be considered as primarily benefiting the general public.

(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under any of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

(C) Notwithstanding any other provision of law, the defendant shall serve an answer to otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the

withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

(G) In the event of noncompliance with the order of the court, the district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within ten days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, "unusual circumstances" means, but only to the extent reasonably necessary to the proper processing of the particular request—

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for

records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such request.

(b) This section does not apply to matters that are—

(1) (A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the

case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include—

(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by such agency regarding this section;

(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and

(7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsections (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(e) For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383; Pub.L. 90-23, § 1, June 5, 1967, 81 Stat. 54; Pub.L. 93-502, §§ 1-3, Nov. 21, 1974, 88 Stat. 1561-1564; Pub.L. 94-409, § 5(b), Sept. 13, 1976, 90 Stat. 1247.

HEW REGULATIONS GOVERNING ADMINISTRATION OF
GRANT RESEARCH

Title 45—Public Welfare

Subtitle A—Department of Health, Education, and Welfare

Part 6—Inventions and Patents (General)

§ 6.1 Publication or patenting of inventions.

It is the general policy of the Department that the results of Department research should be made widely, promptly and freely available to other research workers and to the public. This availability can generally be adequately preserved by the dedication of a Government-owned invention to the public. Determinations to file a domestic patent application on inventions in which the Department has an interest will be made where the circumstances indicate that this is desirable in the public interest, and if it is practicable to do so. Department determinations not to apply for a domestic patent on employee inventions are subject to review and approval by the Commissioner of Patents. Except where deemed necessary for protecting the patent claim, the fact that a patent application has been or may be filed will not require any departure from normal policy regarding the dissemination of the results of Department research.

[23 FR 2990, Mar. 27, 1963. Redesignated at 31 FR 12842, Oct 1, 1966]

Part 8—Inventions Resulting From Research Grants, Fellowship Awards, and Contracts For Research

§ 8.0 Policy.

(a) The Department of Health, Education, and Welfare each year is expending large sums in the form of grants for research. These grants are made primarily by the Public Health Service in carrying out its broad responsibility under the Public Health Service Act to promote and coordinate research in the field of health and to make available information concerning such research and its practical application. The scientific and technological advances attributable, in varying degrees to this expenditure of public funds frequently include patentable inventions.

(b) The Department, as a matter of policy, takes the position that the results of research supported by grants of public moneys should be utilized in the manner which would best serve the public interest. It is believed that the public interest will in general be best served if inventive advances resulting therefrom are made freely available to the Government, to science, to industry, and to the general public.

(c) On the other hand, in some cases it may be advisable to permit a utilization of the patent process in order to foster an adequate commercial development to make a new invention widely available. Moreover, it is recognized that inventions frequently arise in the course of research activities which also receive substantial support from other sources, as well as from the Federal grant. It would not be consistent with the cooperative nature of such activities to attribute a particular invention primarily to support received from any one source. In all these cases the Department has a responsibility to see that the public use of the

fruits of the research will not be unduly restricted or denied.

(d) The following conditions have been adopted to govern the treatment of inventions made in these various types of situations. They are designed to afford suitable protection to the public interest while giving appropriate recognition to the legitimate interests of others who have contributed to the invention.

§ 8.1 Conditions to be included in research grants.

Subject to legislative directives or Executive orders providing otherwise, all grants in aid of research shall provide as a condition that any invention arising out of the activities assisted by the grant shall be promptly and fully reported, and shall provide either

(a) That the ownership and manner of disposition of all rights in and to such invention shall be subject to determination by the Assistant Secretary (Health and Scientific Affairs) or

(b) That the ownership and disposition of all domestic rights shall be left for determination by the grantee institution in accordance with the grantee's established policies and procedures, with such modifications as may be agreed upon and specified in the grant, provided the Assistant Secretary (Health and Scientific Affairs) finds that these are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties, and provided the Government shall receive a royalty-free license, with a right to issue sublicenses as provided in § 8.3, under any patent applied for or obtained upon the invention.

(c) Wherever practicable, any arrangement with the grantee pursuant to paragraph (b) of this section shall provide in accordance with Executive Order 9865 that there be reserved to the Government an option, for a period to be

prescribed, to file foreign patent applications upon the invention.

[20 FR 6749, Sept. 14, 1965, as amended at 31 FR 12842, Oct. 1, 1966]

Part 74—Administration of Grants

Subpart D—Retention and Custodial Requirements for Records

§ 74.20 Length of retention period.

HEW will not impose record retention requirements over and above those established by the grantee except that financial records, supporting documents, statistical records, and all other records pertinent to an HEW grant shall be retained for a period of three years. This requirement applies to the pertinent records and documents of grantees, subgrantees, and recipients under grants or subgrants of negotiated contracts (or subcontracts) exceeding \$10,000. The requirement is qualified as follows:

(a) If audit by or on behalf of the Federal Government has begun but is not completed at the end of the three-year period, or if audit findings have not been resolved at the end of the three-year period, the records shall be retained until resolution of the audit findings. In no case, however, will HEW require retention of records relating to any grant with respect to which actions by the United States to recover for diversion of money paid under the grant are barred by the statute of limitations in 28 U.S.C. 2451(b).

(b) In order to avoid duplicate recordkeeping, granting agencies may make special arrangements with grantees to retain any records which are continuously needed for joint use. The granting agency will request transfer of records to its custody from grantees when it determines that the records possess long-term retention value. When the rec-

ords are transferred to or maintained by HEW, the three year retention requirement is not applicable to the grantee.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.23 Access to records.

(a) HEW and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the grantee which any of them determine are pertinent to a specific HEW grant, for the purpose of making audit; examination, excerpts and transcripts.

(b) In the case of a subgrant (or negotiated contract or subcontract exceeding \$10,000) under a HEW grant, the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee (or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the subgrantee or contractor or subcontractor) which the grantee, HEW, the Comptroller General of the United States, or any of their duly authorized representatives determine are pertinent to the specific HEW grant, for the purpose of making audit, examination, and transcripts.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44552, Oct. 8, 1976]

§ 74.24 Restrictions on public access.

Unless otherwise required by law, HEW will not place restrictions on grantees which will limit public access to the grantee's records or to the records of their subgrantees

or contractors, except when the records must remain confidential for any of the following reasons:

(a) To prevent a clearly unwarranted invasion of personal privacy;

(b) To comply with an executive order or statute which specifically requires the records to be kept secret; or

(c) To protect commercial or financial information obtained from a person or firm on a privileged or confidential basis.

[38 FR 26275, Sept. 19, 1973, as amended at 41 FR 44553, Oct. 8, 1976]

**Pertinent FDA Regulations Governing Maintenance of Records
and Disclosure of Data**

Chapter I—Food and Drug Administration

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published pursuant to § 12.35, the director of the bureau responsible for the matters involved in the hearing shall submit to the Hearing Clerk:

(1) The relevant portions of the administrative record of the proceeding up to that time. Those portions of the administrative record of the proceeding which are not relevant to the issues to be considered at the public hearing shall not be placed on public display and shall not be part of the administrative record of that proceeding.

(2) All documents in his files containing factual data and information, whether favorable or unfavorable to his position, which relate to the issues involved in the hearing.

(3) All other documentary data and information on which he relies.

(4) A narrative statement of his position on the factual issues stated in the notice of hearing and the type of evidence he intends to introduce in the hearing in support of his position.

(5) A signed statement that, to the best of his knowledge and belief, the submission complies with the requirements of this section.

(b) Within 60 days after the notice of hearing is published in the FEDERAL REGISTER pursuant to § 12.35, or, where no participant will be prejudiced, within such shorter or longer period of time as the presiding officer orders, each

participant shall submit to the Hearing Clerk all data and information specified in paragraph (a) (2) through (5) of this section, and any objections with respect to the completeness of the administrative record filed pursuant to paragraph (a) (1) of this section.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been foreseen at that time.

(d) The failure to comply with the provisions of this section in the case of a participant shall constitute a waiver of the right to participate further in the hearing and in the case of a party shall also constitute a waiver of the right to a hearing.

(e) Any documentary data and information submitted by one participant may be referenced by another. Participants are encouraged to exchange and consolidate lists of documentary evidence prior to reproducing it for submission to the Hearing Clerk in order to reduce duplicative submissions. If a particular document is bulky or is in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, a participant may request the presiding officer for permission to submit a reduced number of copies to the Hearing Clerk.

(f) The presiding officer shall rule on questions relating to this section.

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

* * * * *

§ 20.64 Investigatory records compiled for law enforcement purposes.

(c) Any investigatory record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in Subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

* * * * *

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to Subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member

of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by § 312.1(a) (3) of this chapter or other regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

* * * * *

Part 20—Public Information

Subpart F—Availability of Specific Categories of Records

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

Title 21—Food and Drugs

Chapter I—Food and Drug Administration

Part 312—New Drugs For Investigational Use

Subpart A—Exemptions From Section 505(a)

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

• • •

(4) The sponsor maintains adequate records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of a scientifically trained and properly authorized employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in paragraph (a)(2) of this section available for inspection, and upon written requests submits such records or copies of them to the Food and Drug Administration. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970 adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

• • •

(13) The sponsor shall obtain from each investigator involved in clinical trials a signed statement in the following form:

Form FD-1573

Department of Health, Education, and Welfare, Food and
Drug Administration

Statement of Investigator

• • •

4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipts and use of this investigational drug:

• • •

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new drug application is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.

SEP 7 1979

MICHAEL BODAK, JR., CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1978

PETER H. FORSHAM, ET AL., PETITIONERS

v.

PATRICIA R. HARRIS, SECRETARY OF HEALTH,
EDUCATION, AND WELFARE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE DISTRICT
OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS

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In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1118

PETER H. FORSHAM, ET AL., PETITIONERS

v.

PATRICIA R. HARRIS, SECRETARY OF HEALTH,
EDUCATION, AND WELFARE, ET AL.

*ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE DISTRICT
OF COLUMBIA CIRCUIT*

BRIEF FOR THE FEDERAL RESPONDENTS

OPINIONS BELOW

The opinion of the court of appeals (App. 217-257) is reported at 587 F.2d 1128. The order of the district court (App. 180-181) is not reported.

JURISDICTION

The judgment of the court of appeals was entered on July 11, 1978. A petition for rehearing was denied on October 17, 1978 (App. 258-260). The petition for a writ of certiorari was filed on January 15, 1979, and was granted on May 14, 1979. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the Freedom of Information Act requires an agency to acquire and make available to the public records generated, owned and possessed by a private, non-government group, where (a) the records were prepared in the course of a study that received a federal financial assistance grant, (b) in proposing regulatory action the agency relied on a public report of the study based on the records, and (c) the agency has a right under the grant to inspect the records.

STATUTE INVOLVED

5 U.S.C. 552 provides in part:

(a)(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

* * * * *

(a)(4)(B) On complaint, the district court of the United States in the district in which the complainant resides, or has his principal place of business, or in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. * * *

STATEMENT

1. In mid-1959 a group of private, non-government physicians and scientists specializing in the treatment of diabetes at 12 participating clinics formed the University Group Diabetes Program (UGDP) to perform a long-term study comparing the incidence and development of degenerative complications of diabetes mellitus (App. 145-146). Initially, the UGDP study involved four treatment regimens: (1) diet alone; (2) diet plus insulin in standard dose; (3) diet plus insulin in variable dose; and (4) diet plus tolbutamide. In 1963 a fifth regimen was added: diet plus phenformin hydrochloride (App. 146). Tolbutamide and phenformin are administered orally and belong to a class of drugs known as "oral hypoglycemic" drugs.¹

Since 1961 the UGDP study has received federal funding from the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) under the Public Health Service Act, 42 U.S.C. 241(c) (App. 145-147). Representatives of NIAMDD evaluated the design, methods and objectives of the study in its formative stages and periodically reviewed UGDP progress reports in connection with grant renewals (App. 146-147). However, management of

¹ Oral hypoglycemic drugs fall into two categories: the sulfonylurea category (represented by tolbutamide) and the biguanide category (represented by phenformin hydrochloride). Both categories of drugs reduce blood-sugar levels in diabetic patients but operate through different biological mechanisms. See 40 Fed. Reg. 28587 (1975).

the day-to-day operations of the study remained the responsibility of UGDP. NIAMDD's supervision of the grantee's funded activities was generally limited to review of the periodic reports submitted by UGDP (see 45 C.F.R. 74.80, 74.82) (App. 147). The Food and Drug Administration was not involved in the planning, implementation, or design of the study (App. 146).²

By 1973, based on observations of over 1000 diabetes patients, the UGDP study had generated approximately 55 million documents. At all times these patient records have been in the possession of UGDP (App. 148). This information belongs to UGDP, and the NIAMDD grants and related regulations do not purport to shift ownership to the agency (App. 147, 180, 198). Moreover, although NIAMDD has a right to inspect the data to ensure compliance with the grant (see 45 C.F.R. 74.24), it has never seen or had possession of the originals or copies of the patient records (App. 148).

² The National Institute of Arthritis, Metabolism and Digestive Disorders is one of several Institutes of the National Institutes of Health (NIH). It is authorized by statute to conduct and fund research on diabetes and other diseases. 42 U.S.C. 289a, 289c-1. The Food and Drug Administration (FDA) is a separate agency charged with enforcement of the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, including requirements for the labeling of drug products. NIAMDD and FDA are components of the Public Health Service, which is itself a part of the Department of Health, Education, and Welfare. See Reorganization Plan No. 3 of June 25, 1966, 31 Fed. Reg. 8855, and Reorganization Order of April 1, 1968, 33 Fed. Reg. 5426.

2. The Food and Drug Administration has initiated two proceedings to regulate oral hypoglycemic drugs. First, FDA has proposed to require a warning on the use of such drugs.³ In 1970, UGDP reported a finding that the administration of tolbutamide to adults who had developed mild cases of diabetes led to a death rate from cardiovascular disease higher than that of a group treated with diet alone or with a fixed or variable dosage of insulin (App. 6, 222).⁴ In 1971, UGDP reported a similar finding on phenformin.⁵ Four years later, UGDP reported in more detail that phenformin-treated groups developed increased blood pressure levels and heart rate, thus suggesting that the drug might influence cardiovascular mortality.⁶ Based in part on these reports, FDA proposed to require a label warning that oral

³ Pursuant to 21 U.S.C. 352(a), (f), 355(b), (d) (6) and (e) (3), FDA regulates the content of drug labeling. In practice, labeling includes detailed literature prepared and distributed by manufacturers to instruct physicians on the use of the drug. See 21 C.F.R. 201.100.

⁴ Klimt, Knatterud, Meinert & Prout, *The University Group Diabetes Program: A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes*, 19 Diabetes 747 (Supp. 2, 1970).

⁵ UGDP, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes. IV. A Preliminary Report on Phenformin Results*, 217 J.A.M.A. 777-784 (1971).

⁶ UGDP, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes. V. Evaluation of Phenformin Therapy*, 24 Diabetes 64-184 (Supp. 1, 1975).

hypoglycemics should be used only in cases of adult-onset, stable diabetes that could not be treated adequately by diet and/or insulin. 40 Fed. Reg. 28587, 28591 (1975). This proposal has not yet become final.⁷

⁷ The FDA first proposed label changes for tolbutamide and other sulfonylurea drugs in 1971. FDA Drug Bulletin (June 23, 1971). In response to criticisms of the UGDP study within the scientific community, NIAMDD contracted in 1972 with the Biometric Society, a private international society of biostatisticians, for an in-depth independent assessment of the quality of the UGDP study (App. 148). The Biometric Society reviewed a portion of the original patient data, among other things, and concluded that the "UGDP trial has raised suspicions [concerning the adverse effects of oral hypoglycemic drugs] which cannot be dismissed on the basis of other evidence presently available" and that "we consider the evidence of harmfulness moderately strong." *Report of the Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents*, 231 J.A.M.A. 583-608, 599 (1975). The contract with the Biometric Society did not require either that the Society seek access to the UGDP raw data or that any raw data that it did review be transmitted to NIAMDD. At the conclusion of its assessment, the Society did not submit to NIAMDD any raw data pertaining to UGDP (App. 148).

On July 7, 1975, the FDA published a summary of the findings of the Biometric Society, restated its intention to require the labeling change (including a label change for phenformin), and invited public comment. 40 Fed. Reg. 28587 (1975). Thereafter, in response to further criticisms of the UGDP study and of the Society's audit (see App. 250-251 n.17), the FDA (pursuant to a delegation of NIAMDD's authority to audit grantee records) conducted its own audit of the UGDP study. The FDA's audit team's conclusions were similar to those of the Biometric Society: although there were some errors and some discrepancies between the data file of the UGDP study and the published reports, the errors were not of sufficient frequency or magnitude to invalidate the finding that cardiovascular mortality was higher in the groups of

Second, on July 25, 1977, in light of numerous reports on the dangers of phenformin, the Secretary (acting pursuant to the imminent-hazard provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e))) suspended approval of new drug applications for phenformin until completion of administrative proceedings on the withdrawal of the applications.⁸ On November 15, 1978, the FDA found that phenformin was not shown to be safe and ordered it withdrawn from the market. This decision, which superseded the Secretary's imminent-hazard order, was not based substantially on the UGDP study.⁹

patients treated with tolbutamide plus diet and phenformin plus diet than in the groups treated with placebo or insulin. In conducting this audit, the FDA examined and copied a small but statistically adequate sample of the UGDP raw data. On November 14, 1978, FDA announced that its audit report was available for public inspection and that it had reopened the comment period on the labeling changes. 43 Fed. Reg. 52733 (1978). At the request of various parties the comment period has been further extended to September 14, 1979, and the labeling change has not yet become final and effective. 44 Fed. Reg. 42714 (1979).

⁸ Contrary to petitioners' argument (Br. 17), the Secretary's order was not based "primarily" on the UGDP "data." The UGDP data were not examined by the Secretary at all. Instead, the UGDP study was listed as one of many reporting the dangerous effects of phenformin. See Order of the Secretary of Health, Education and Welfare, July 25, 1977, at 8-9.

⁹ The order of the Commissioner of Food and Drugs, dated November 15, 1978, stated in part (44 Fed. Reg. 20969 (1979)):

I affirm the Administrative Law Judge's ruling on the motion to strike the UGDP data. The Administrative Law Judge held that the "lack of availability of underlying data casts considerable doubt on the reliability of the

UGDP conclusions from an evidentiary standpoint. To the extent such data was not made available, the UGDP conclusions cannot be considered as substantiated on the record." * * * Accordingly, in reviewing the Bureau's evidence on the question of safety, the Administrative Law Judge referenced the UGDP study in only one paragraph of his 8-page summary. Initial Decision, at 20.

The Administrative Law Judge concluded that the UGDP study could be used for two purposes: to raise questions about the safety of phenformin and as the basis for expert opinion. The FDA has long taken the position that evidence suggestive of a lack of safety may be considered in evaluating whether a drug has been shown to be safe even though the evidence does not meet the standards required to establish the safety of the drug. The Administrative Law Judge's ruling that the UGDP study might serve as the basis for expert testimony is supported by Rule 703 of the Federal Rules of Evidence, which provides that even if data are not admissible into evidence they may nevertheless form the basis of opinions by experts if they are the type of data reasonably relied upon by experts in that particular field.

* * * * *

The record in this proceeding includes nearly 400 articles published in the medical literature. Many of them report studies on phenformin. None of those articles is accompanied by the "raw data" upon which it is based. The Bureau has relied solely on the published report of the UGDP study in the same way that it has relied upon the other published articles that were admitted into evidence. 21 C.F.R. 12.85 requires only that the Bureau provide data upon which it relies; it does not require the Bureau to submit related data on which it does not rely.

Because of CCD's emphasis on the unavailability of the raw data underlying the UGDP study, I have reviewed the testimony of the Bureau of Drugs' expert witnesses and find that their reliance upon the UGDP study was not substantial and cannot reasonably be characterized as pivotal to the opinions expressed by those witnesses.

44 Fed. Reg. 20967-20991 (1979).¹⁰

3. Petitioners are three members of the Committee on the Care of the Diabetic (CCD), an unincorporated association of physicians who treat diabetes, who contend that the UGDP study is unreliable (App. 4).¹¹ Prior to September 30, 1975, CCD made several Freedom of Information Act requests to the FDA and NIAMDD for access to, among other things, the UGDP original raw patient data (App. 40, 42-43, 49-52, 55-56, 59-60, 61-62). Both agencies responded that neither they nor any other branch of HEW had seen or possessed the materials requested, that the data belonged to UGDP, a private group, and therefore were not "agency records," and that the agencies were not required to acquire and produce them under the FOIA (App. 54, 57). All other requested documents related to the study in the possession of the agencies, including a limited sample of the patient data acquired by the FDA and the UGDP draft

¹⁰ On April 10, 1979, the court of appeals held that petitioners lack standing to challenge the FDA's withdrawal of phenformin's new drug application. The court also held that this disposition rendered moot the appeal from the district court's denial of a preliminary injunction against the Secretary's imminent-hazard order. *Forsham v. Califano*, Nos. 77-2072 and 78-2288 (D.C. Cir. filed Apr. 10, 1979).

¹¹ Petitioners present their side of this controversy in considerable detail. Because the controversy is irrelevant to petitioners' claims under the Freedom of Information Act (see page 49, *infra*), we see no need to engage in an academic debate on the subject. The arguments in support of the UGDP findings may be found in references listed at App. 250 n.15.

and final reports, were made available to CCD (App. 143, 225).

On September 30, 1975, petitioners filed this FOIA suit in the United States District Court for the District of Columbia to require HEW to acquire and make available to them all of the raw patient data compiled by UGDP (App. 1).¹² The district court granted summary judgment in favor of the defendants, holding that the patient data are not "agency records" within the meaning of the FOIA (App. 180-181; footnote omitted):

[T]he Court finds that (1) no official or employee of the Department of Health, Education and Welfare (HEW), the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the National Institutes of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is now or has ever been in possession of raw data in issue relating to the University Group Diabetes Program (UGDP) * * *; (2) the raw data in question is the property of the individual investigators and UGDP study coordinating center and remains in the possession, custody and control of the UGDP study coordinating center * * *; (3) neither the individual investigators nor the UGDP study coordinating center is an "agency" within the purview of the Freedom of Information Act, 5 U.S.C. § 552; and (4) consequently, the raw data in issue are

¹² The complaint also named Dr. Christian Klimt, director of the UGDP coordinating center at the University of Maryland School of Medicine, as a defendant (App. 5). As director, Dr. Klimt has actual possession of the data (App. 5, 180).

not "agency records" subject to the disclosure provisions of the Freedom of Information Act

* * *

The court of appeals affirmed, concluding that the "public at large does not have a right under the Freedom of Information Act to the underlying raw data in the hands of the investigators and university groups who conducted the UGDP study program of diabetes under grants from the federal government" (App. 225-226). The court rejected petitioners' argument that the UGDP data are "agency records" because (i) the study that led to the data was entirely funded by the federal government, (ii) the data were available to the FDA and NIAMDD for copying and inspection, and (iii) the FDA had based regulatory decisions on the conclusions (although not on the underlying data) of the UGDP study.

Concerning the first factor, the court held that private grantees do not become federal agencies merely because they receive federal funds. Grantee autonomy persists despite the funding (App. 228-229, 233-235). Only where the government is involved "in the core planning or execution of the program," the court observed, may the recipient of a grant be considered a federal agency for purposes of the FOIA (App. 232 n.19 and 237). Concerning the second factor, the court noted that NIAMDD was not required to inspect and copy the data merely because it had a limited right to do so. A contrary rule, the court noted, would contravene the established principle that the FOIA does not oblige agencies to create records on request (App. 231-232).

Concerning the third factor, the court stressed that "need, interest or public interest" have no bearing on access under the FOIA (App. 226). If an agency were to rely on the conclusions of a private study whose underlying data it had not examined, the court suggested that the agency's action could be challenged as arbitrary, depending on the circumstances, under well-established mechanisms independent of FOIA (App. 226-227 n.11).

Judge MacKinnon concurred in the court's opinion, except for the portion suggesting that the Freedom of Information Act would apply not only to records in the possession of an agency but also to records the agency has a duty to obtain. As to records not in the possession of an agency, he stated, the application of the Act should be determined case-by-case (App. 238-239).

Judge Bazelon dissented. He noted that the federal government provided all funding for the UGDP study, the government has a right of access to the data, and the government had relied on the study and data in taking "regulatory action dealing with the treatment of diabetes" (App. 249). Under these circumstances, Judge Bazelon concluded that the "degree of federal involvement with the UGDP raw data" (App. 240) is sufficiently great that they should be treated as agency records for purposes of the FOIA.

INTRODUCTION AND SUMMARY OF ARGUMENT

Neither the Department of Health, Education, and Welfare, nor any of its relevant components—FDA, NIH and NIAMDD—has ever had ownership, custody or control of the UGDP patient data at issue in this case (App. 147, 180).¹³ The records have at all times been owned and possessed by the UGDP coordinating center and its director, Dr. Klimt (App. 69, 180). The UGDP coordinating center is a private, non-government organization, not a federal agency. These conclusions are undisputed. In our view they are dispositive.

I.

The FOIA grants any person a right to inspect any reasonably identifiable nonexempt record in the custody and control of a federal agency. It establishes no right to inspect records owned by private individuals or groups and in their custody and control. This is clear from the plain language and structure of the Act and from its legislative history.¹⁴

¹³ The data copied by the FDA during its audit of UGDP have been provided to petitioners (App. 225). At issue here are only the data not copied by any federal agency and still in the exclusive possession of UGDP.

¹⁴ A document is in the custody and control of an agency not only when the agency has possession of the document but also when the document is bailed or loaned to a private individual, another agency, or any other party who agrees to return it on request. Thus, an agency may not defeat FOIA disclosure by storing documents in a private warehouse rather than a federal records center (see App. 232 n.19).

Where, however, a document claimed to be an agency record is held by someone other than the agency under a claim of

A. The FOIA "makes available" to the public all nonexempt "agency records." 5 U.S.C. 552(a)(3). If "agency records" are improperly "withheld," the

rightful possession, the agency is deprived of custody and control until the document is returned. In such circumstances, if a request is made to the agency for the missing materials, the agency does not "withhold" records within the meaning of the FOIA by not commencing legal proceedings for the return of the documents. This is true even if the agency arguably "owns" the documents or if they are arguably "records" under the Federal Records Act, 44 U.S.C. 3301, such that the agency is required to request the Attorney General to commence legal action to retrieve them (see 44 U.S.C. 3106). Thus, in *Kissinger v. Reporters Committee for Freedom of the Press*, Nos. 78-1088 and 78-1217, we argue that the Department of State did not "withhold" telephone notes made by Secretary Kissinger of his telephone conversations and donated by him to the Library of Congress before any FOIA request for them had been made merely because the State Department did not seek their return from the Library of Congress in order to satisfy the FOIA request. This is true even if the notes are "records" required to be preserved by the agency under Federal Records Act, 44 U.S.C. 2901 *et seq.* As Judges Leventhal and MacKinnon observed (App. 232 n.18, 238), however, the present case does not present any issue concerning an agency's duty under the FOIA to retrieve documents that it owns or that it is under a separate duty to obtain.

Although the issue is not presented by this case, in our view the requirement of "control" has force independent of the requirement of "custody." Thus, in *Goland v. CIA*, No. 76-1800 (D.C. Cir. May 28, 1978), *pet. for cert. pending*, No. 78-1924, we argue that where the House of Representatives loans an agency a transcript of an executive session hearing, stamps it "secret" and retains ownership and control of it, the transcript does not become an "agency record" under the FOIA merely because it is in the custody of the agency. The agency must also have sufficient control over the document to release it to the public. In *Goland* such authority has been exclusively retained by the House of Representatives.

complainant may sue to enjoin such "withholding." 5 U.S.C. 552(a)(4)(B). The Act does not define these terms, but their meaning is plain. "Agency records" means records of a federal agency. An agency does not "withhold" what it cannot produce—that is, what it does not have in its custody and control. If a document is outside the custody and control of a federal agency because, as here, it is owned and possessed by a private group, the FOIA does not require the agency to obtain and produce it for public inspection.

B. The legislative history reinforces this construction of the Act. The FOIA was provoked by a clearly delineated problem—prior law, principally Section 3(c) of the Administrative Procedure Act of 1946, 60 Stat. 238, gave federal agencies broad and unreviewable discretion to shield their documents from public view. Section 3 only required agencies to make available "matters of official record" to any person "properly and directly concerned" and permitted nondisclosure whenever, in the agency's view, "good cause" or "the public interest" demanded secrecy. By 1966, Congress concluded that these qualifications had led to widespread and unjustified withholding of requested agency documents. Abuse after abuse was cited in the legislative hearings and debates. Each was an example of an agency's refusal to divulge a record in its custody and control. To solve this problem, Congress in the FOIA prohibited "withholding" of "agency records" and replaced the agencies' discretion to withhold with nine specific exemptions. In

light of the discrete problem solved by the FOIA, the scope of the solution gathers precise meaning: non-exempt records in an agency's possession and control must be made available. The Act has no application to any other documents.

Other portions of the legislative history are consistent with this interpretation. The committee hearings and reports and the statements of individual legislators uniformly described the FOIA as comprehending "materials of the government," "executive branch records," "government documents" and materials "submitted to" or "controlled by" the government. Not once is there a suggestion that federal agencies would be obliged to procure and make available documents owned and possessed by private parties, regardless of the relationship between those documents and the government's business.

Indeed, the assumption that the Act comprehended only records in an agency's possession is made clearest in the comments of the agencies themselves. A number of agencies opposed passage of the FOIA, arguing chiefly that the law would impose a huge administrative burden in light of the volume of federal records and that retaining agency discretion to preserve secrecy on a case-by-case basis was wiser than enacting nine specific exemptions. If the agencies had ever imagined that these burdens would also extend to the billions of additional documents in the private sector that are "available" to an agency in reaching regulatory decisions or that have some nexus with public policy, they undoubtedly would have

voiced their objections loudly. The silence on this issue speaks volumes.

C. The structure of the FOIA also supports a limitation on its operation to documents in the custody and control of a federal agency. Several of the exemptions would make little sense if the Act applies to records outside an agency's possession. Exemption 4, for example, maintains the confidentiality only of trade secrets or commercial information "obtained from a person," while Exemption 8 preserves the secrecy of financial reports prepared by financial institutions "for the use of [a supervising] agency," without exempting the identical reports in the hands of the institutions themselves.

The procedural provisions of the Act convey the same interpretation. The stringent time limitations of 5 U.S.C. 552(a)(6) may be extended to allow an agency to consult with "another agency" interested in the disclosure of particular records. Agency employees may be punished by the court for contempt or disciplined for wrongful withholding of records, 5 U.S.C. 552(a)(4)(F), (G). No parallel authority is provided to allow consultation with private individuals or groups owning or possessing requested documents or to discipline private parties who thwart court orders to produce such documents. Obviously, such provisions were thought unnecessary because the Act was never intended to require the production of materials outside the custody and control of the government.

II.

The Court should reject petitioners' invitation to create an exception to the agency custody-and-control rule in this case because HEW (i) funded and "participated in" the design of the UGDP project, (ii) has access to the raw patient data for the purpose of auditing the project, and (iii) relied on reports of the UGDP study (but not the underlying data) for regulatory purposes. Individually and collectively, these factors do not warrant a deviation from the bright line drawn by Congress in defining what are "agency records" subject to the FOIA.

A. The fact that the UGDP project received federal funds cannot serve as a basis for applying the Act to the documents generated by that private group. In amending the definition of "agency" in 1974, Congress made clear that non-government organizations are not covered by the FOIA merely because they receive federal monies. H.R. Conf. Rep. No. 93-1380, 93d Cong., 2d Sess. 14-15 (1974). Nor does the agency's routine regulation and review of grantee activities make it a "partner" of the UGDP or deprive the grantee of exclusive ownership of the project's documents. HEW's oversight function here was limited to ensuring that a recipient of substantial federal funding was proceeding in a way designed to benefit the public interest. Moreover, HEW regulations state that title to grantee records vests in the grantee. 45 C.F.R. 74.132-74.133.

B. The UGDP documents are not "agency records" within the FOIA because the agency may have a right

of access to the documents under other statutes or regulations or under the terms of the grant. First, the agency's inspection rights are limited to specified purposes other than providing general access to the public. In addition, even if the agency were authorized to inspect and copy the raw patient data for reasons unrelated to the grant, such copying would not be required by the FOIA, which repeatedly has been held not to require the government to create records in response to requests. *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 161-162 (1975). Finally, there is hardly a document in the United States that is not subject to subpoena, summons or civil investigative demand. If agency access is a relevant criterion, the FOIA would reach large numbers of private materials related to public policy issues. Congress obviously intended no such result.

C. Nor does it matter that the agency relied on the reports and audits of the UGDP study for regulatory purposes. Every UGDP record actually considered by the agency in reaching its decisions has been fully disclosed. Petitioners want to see underlying data that even the agency has not seen. It goes without saying, however, that the FOIA does not create a right to know what even the government does not know. Even in its widest cast, the purpose of the Act was to disclose agency action and the materials viewed by the agency in taking that action. That purpose has been fully vindicated here.

D. Finally, the whole of petitioners' "congeries of considerations" (App. 230) is less than the sum of

its parts, for in its totality it transgresses Congress' fundamental purpose to eliminate the vague phrases that previously had governed agency disclosure and to replace them with a well-defined rule of complete disclosure of "agency records" subject only to nine discrete exemptions. Petitioners' approach, by relying on subjective factors such as "significant agency participation" and "agency reliance," reintroduces the very evil Congress sought to avoid in the FOIA. The bright line established by the Act—whether the documents are in the custody and control of a federal agency—is faithful to the statutory language and purpose, easy to apply and invites none of the controversy and litigation that would inevitably result from petitioners' balancing test.

ARGUMENT

The original patient records and related documents at issue in this case have at all times been owned and possessed by the private clinics conducting the UGDP study, by the UGDP coordinating center, and by the center's director, Dr. Klimt (App. 180). If UGDP were an "agency" under the Freedom of Information Act, then UGDP upon request would be required to make available to petitioners all nonexempt portions of its raw data. The FOIA, however, defines "agency" as "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regula-

tory agency." 5 U.S.C. 552(e). UGDP fits none of these descriptions.

The legislative history of the Act confirms that a private organization, even one receiving a federal financial assistance grant, is not an "agency." The Conference Committee Report on the 1974 amendments remarks (S. Conf. Rep. No. 93-1200, 93d Cong., 2d Sess. 14-15 (1974) (emphasis added)):

The conferees state that they intend to include within the definition of "agency" those entities encompassed by 5 U.S.C. 551 and other entities including the United States Postal Service, the Postal Rate Commission, and government corporations or government-controlled corporations now in existence or which may be created in the future. *They do not intend to include corporations which receive appropriated funds but are neither chartered by the Federal Government nor controlled by it, such as the Corporation for Public Broadcasting.*

UGDP is not a "government controlled corporation." It receives federal monies, but that fact, as mentioned above, is not enough to make it an "agency" within the meaning of Section 552(e).¹⁵ See *Ciba-*

¹⁵ For purposes other than the FOIA, the receipt of federal funds has been held not to render an otherwise private organization a federal agency. See, e.g., *Spark v. Catholic University*, 510 F.2d 1277 (D.C. Cir. 1975) (federal question jurisdiction); *Wahba v. New York University*, 492 F.2d 96 (2d Cir.), cert. denied, 419 U.S. 874 (1974) (applicability of constitutional limitations on discharge of employee working on grant-related project). See generally *United States v. Orleans*, 425 U.S. 807 (1976) (extent of liability of the United States

Geigy Corp. v. Mathews, 428 F. Supp. 523, 530 (S.D.N.Y. 1977).¹⁶

Significantly, petitioners do not contend that UGDP is a federal agency (see App. 255 & n.22). They instead rest their FOIA claim on the argument that the patient data are "records" of the Department of Health, Education, and Welfare, and that HEW must acquire the data from UGDP so that petitioners may examine them.¹⁷ Petitioners urge (Br. 23-24) this

under Federal Tort Claims Act for federal grantees' actions depends on whether day-to-day control exists).

¹⁶ For decisions holding various private entities not to be "agencies" within the FOIA, see *Washington Research Project v. Department of HEW*, 504 F.2d 238, 248 (D.C. Cir. 1974), cert. denied, 421 U.S. 963 (1975) (peer review group advising a federal agency); *Ciccione v. Waterfront Com'n of New York Harbor*, 438 F. Supp. 55, 58 (S.D.N.Y. 1977) (Waterfront Commission of New York Harbor); *Lombardo v. Handler*, 397 F. Supp. 792, 793-795 (D.D.C. 1975), aff'd, 546 F.2d 1043 (D.C. Cir. 1976), cert. denied, 431 U.S. 932 (1977) (National Academy of Sciences); *Gates v. Schlesinger*, 366 F. Supp. 797 (D.D.C. 1973) (Defense Advisory Committee on Women in the Services); *Independent Investor Protective League v. New York Stock Exchange*, 367 F. Supp. 1376 (S.D.N.Y. 1973) (New York Stock Exchange). For a decision holding a government corporation to be an agency within the FOIA, see *Rocap v. Indiek*, 539 F.2d 174, 177 (D.C. Cir. 1976) (Federal Home Loan Mortgage Corporation).

¹⁷ Actually, although petitioners frequently state that the data are "agency records" (see Br. 23, 24, 25, 26, 27), they do not identify expressly the "agency" to which the records allegedly belong. Because petitioners sued officials of HEW, however, we assume that petitioners' references to "the government," "governmental access," "government direction and involvement" and similar generalized references refer to HEW or one of its component agencies.

result due to the confluence of three factors: (i) HEW was "significantly involved" in the design, implementation and policy direction and funding of the UGDP study, (ii) the agency enjoys a right of access to the data, and (iii) the agency has relied on the data for purposes of "regulatory decision making."

This argument fails for two reasons. First, the FOIA requires production only of records in the custody and control of a federal agency. It does not reach documents generated and held by private individuals, no matter how relevant those documents might be to the affairs of a federal agency. Second, considered both individually and in combination, the three factors identified by petitioners do not warrant the creation of an exception to the bright-line custody-and-control rule.

I. THE FOIA REQUIRES FEDERAL AGENCIES TO MAKE AVAILABLE ONLY RECORDS IN THEIR CUSTODY AND CONTROL

A. The Plain Language Of The Act Limits An Agency's Disclosure Obligations To Documents In Its Custody And Control

As this Court has repeatedly noted, the "starting point in every case involving the construction of a statute is the language itself." *Southeastern Community College v. Davis*, No. 78-711 (June 11, 1979), slip op. 6. The FOIA requires federal agencies to make all nonexempt "agency records" available for inspection by the public. It prohibits "withholding" of such records. If an agency improperly withholds a document subject to disclosure, the requester may

sue to enjoin the "withholding." 5 U.S.C. 552(a)(3), (a)(4)(B).

Congress found it unnecessary to define these terms more precisely because they plainly refer to documents in an agency's custody and control. "Agency records" obviously means records of a federal agency. "Withholding" cannot occur if the agency does not have the documents to produce. This is the interpretation of the Act adopted in the Attorney's General's contemporaneous memorandum explaining the provisions of the FOIA. *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (1967). And, it was the view of the Court in *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 221 (1978), describing the Act as reaching "records and material in the possession of federal agencies * * *." In short, the language of the Act plainly draws the line at documents in agencies' custody and control (see note 14, *supra*). As we now show, the legislative history and the overall structure of the FOIA also compel this conclusion.

B. The Legislative History Of The Act Confirms That An Agency Need Not Obtain Records From Private Organizations In Order To Satisfy An FOIA Request

No one would have been more surprised than the members of the 89th Congress to learn that the FOIA established a public right to review papers owned and possessed by private individuals. To be sure, the Act advanced significantly the public's right to learn of federal agencies' actions and of the materials considered by the agencies in taking those actions. The significant advances of the Act, however, were the

elimination of the previous rule that had permitted agencies broad and unreviewable discretion to withhold from public scrutiny records that unquestionably were in their custody and control and the establishment of an unqualified and enforceable right of "any person" (5 U.S.C. 552(a)(3)) to inspect all nonexempt and identifiable agency records. There is no evidence to suggest that the FOIA was ever intended to give the public a right to know information unknown to the government itself.

One of the surest guides in the interpretation of a statute is consideration of the particular mischief that Congress sought to prevent. See, e.g., *Johansen v. United States*, 343 U.S. 427, 431 (1952); *Bindzyck v. Finucane*, 342 U.S. 76, 80-84 (1951). The scope of the FOIA gathers precise meaning in light of the specific defects in the public-disclosure procedures that led first to Section 3 of the Administrative Procedure Act of 1946, 5 U.S.C. (1964 ed.) 1002, and later to the FOIA in 1966. The "public information" section of the APA was provoked by mounting concern that administrative agencies had become an uncontrolled "fourth branch" of government. H.R. Rep. No. 1980, 79th Cong., 2d Sess. 2, 6-15 (1946). A major part of the problem—indeed, "an important and far-reaching defect in the field of administrative law"—was "a simple lack of adequate public information concerning its substance and procedure." *Id.* at 10-11. A House Committee investigating the matter reported that "[i]t is practically impossible for a Member of Congress, much less an individual citizen, to find his way among

these many agencies or to locate the particular officer or employee in any of the agencies with whom any particular problem should be discussed with a view to settlement." *Id.* at 9.

To solve this problem, Section 3 of the APA imposed on federal agencies the duty to publish information concerning their organization, procedures, substantive rules, opinions and orders.¹⁸ In addition, in order "to make access to public records generally applicable, uniform, and more readily determinable" (H.R. Rep. No. 1980, *supra*, at 23),¹⁹ Section 3(c) required that certain "matters of official record" be made available to persons with a "need to know" (60 Stat. 238):

Except to the extent that there is involved (1) any function of the United States requiring secrecy in the public interest or (2) any matter relating solely to the internal management of an agency—

* * * * *

(c) * * * Save as otherwise required by statute, matters of official record shall in accordance with

¹⁸ The overriding purpose of Section 3 was to inform "the general public" about procedures and methods" (H.R. Rep. No. 1980, *supra*, at 21) and "to assist the public in dealing with administrative agencies by requiring agencies to make their administrative materials available in precise and current form." *Attorney General's Manual on the Administrative Procedure Act* 17 (1947). It was "drawn upon the theory that administrative operations and procedures are public property which the general public, rather than a few specialists or lobbyists, is entitled to know * * *." H.R. Rep. No. 1980, *supra*, at 25.

¹⁹ Accord, S. Rep. No. 752, 79th Cong., 1st Sess. 1-4, 6, 12-13 (1945).

published rule be made available to persons properly and directly concerned except information held confidential for good cause found.

Section 3(c) applied, however, only to documents in the custody of an agency; indeed, it applied only to matters of "official record." In 1947, the Attorney General advised federal agencies that "official records" included materials such as "applications, registrations, petitions, reports and returns filed by members of the public with the agency pursuant to statute or the agency's rules" and "all * * * documents embodying agency actions, such as orders, rules and licenses." *Attorney General's Manual on the Administrative Procedure Act* 24-25 (1947). As examples of "official records," the Attorney General's Manual cited "[m]aps, plats or diagrams in the custody of the Secretary of the Interior," "records, books or papers in the General Land Office," "registration statements filed with the Securities and Exchange Commission," and pleadings, transcripts of testimony, exhibits, and all documents received in evidence or made part of the record in official proceedings. *Ibid.* The manual stated, however, that the "great mass of material relating to the internal inspection of an agency is not a matter of official record." *Id.* at 25. One type of document not subject to disclosure was "intra-agency memoranda" prepared for use within the agency. *Ibid.*

Nothing in the language or legislative history of Section 3(c) of the APA, in the Attorney General's Manual, or in the cases decided under that section offers the slightest hint that the statute was designed

to confer on the public a right to inspect documents in the hands of government grantees, contractors or other private persons. The problem addressed by Section 3(c) was far more basic. For the first time, it established a right of "directly concerned" individuals to inspect "official records," such as orders or other evidence of actions taken by an agency and the materials relied on by the agency, except where "good cause" or the "public interest" required secrecy.

Although Section 3 of the APA was a substantial improvement over prior law, the section was generally recognized as falling far short of its disclosure goals and came to be looked upon more as a withholding statute than a disclosure statute. See *EPA v. Mink*, 410 U.S. 73, 79 (1973). The qualifications in Section 3(c) invited abuse, and by 1966 Congress concluded that the section was "full of loopholes which allow agencies to deny legitimate information to the public." S. Rep. No. 813, 89th Cong., 1st Sess. 3 (1965) (Senate Rep.). Specifically, four defects were found (*id.* at 5):

(1) There is excepted from the operation of the whole section "any function of the United States requiring secrecy in the public interest * * *." There is no attempt in the bill or its legislative history to delimit "in the public interest," and there is no authority granted for any review of the use of this vague phrase by Federal officials who wish to withhold information.

(2) Although subsection (b) requires the agency to make available to public inspection "all final opinions or orders in the adjudication of cases," it vitiates this command by adding the following limitation: "* * * except those required for good cause to be held confidential * * *."

(3) As to public records generally, subsection (c) requires their availability "to persons properly and directly concerned except information held confidential for good cause found." This is a double-barreled loophole because not only is there a vague phrase "for good cause found," there is also a further excuse for withholding if persons are not "properly and directly concerned."

(4) There is no remedy in case of wrongful withholding of information from citizens by Government officials.

As a result of these deficiencies, the Senate Report noted, agency officials had actually turned the statute on its head by using it as an excuse to withhold information (Senate Rep. at 5). The Freedom of Information Act sought to close these loopholes by making three "major changes" (Senate Rep. at 5-6):

(1) It sets up workable standards for what records should and should not be open to public inspection. In particular, it avoids the use of such vague phrases as "good cause found" and replaces them with specific and limited types of information that may be withheld.

(2) It eliminates the test of who shall have the right to different information. For the great majority of different records, the public as a whole has a right to know what its Government

is doing. There is, of course, a certain need for confidentiality in some aspects of Government operations and these are protected specifically; but outside these limited areas, all citizens have a right to know.

(3) The revised section 3 gives to any aggrieved citizen a remedy in court.

Hence, the FOIA makes available "to any person" all identifiable agency documents, which it divides into three categories: some must be published in the *Federal Register* (5 U.S.C. 552(a)(1)); others must be published or made publicly available and indexed (5 U.S.C. 552(a)(2)); and all others must be furnished on request (5 U.S.C. 552(a)(3)). The FOIA then defines nine categories of documents to which the Act "does not apply" (5 U.S.C. 552(b)). Finally, the district courts are given "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant" (5 U.S.C. 552(a)(4)(B)).

Three points emerge from this brief discussion to support the conclusion that the FOIA extended the duty to disclose only to "agency" documents in the custody and control of a federal agency. First, Congress identified with precision the failing in the APA "public information" section—agencies were withholding documents in their possession for invalid reasons or for no reason at all. Examples of the abuses noted by Congress included the withholding of agency telephone directories (H.R. Rep. No. 1497, 89th Cong., 2d Sess. 5 (1966) (House Rep.)), the names, positions and salaries of agency employees, cost esti-

mates submitted by unsuccessful contractors to the National Science Foundation, dissents of members of regulatory commissions from official agency actions, and a proposed spending program for an agency (House Rep. at 6). Every example mentioned in the legislative debates and reports was of a document in the unquestioned custody and control of a federal agency.

In response to the "withholding" problem, Congress made clear that the duty to disclose applied to all "agency" records, not just those that the agency deemed "official" or "public,"²⁰ subject only to nine discrete exemptions. But Congress did not criticize, much less alter, the prior rule that agencies did not have to obtain and make available any documents in private hands.²¹ Section 3(c) plainly did not extend that far, but the limitation was of no concern. The term "agency records" in the FOIA must therefore be construed in view of the specific problem Congress did seek to remedy—an agency's refusal to divulge nonexempt records in its possession.

²⁰ Section 3(c) of the APA was entitled "public records" and required "matters of official record" to be made available, subject to the qualifications discussed above. The FOIA used the phrase "agency records" to eliminate any inference that agencies could avoid disclosure of "nonpublic" or "unofficial" files in their custody. See Senate Rep. at 7.

²¹ In subsequent years Congress identified additional deficiencies in the FOIA, but not once has it ever suggested that production of grantee or other private records is an objective of the Act. See generally H.R. Rep. No. 92-1419, 92d Cong., 2d Sess. (1972); S. Rep. No. 93-854, 93d Cong., 2d Sess. (1974) (1974 Sen. Rep.); H.R. Rep. No. 93-876, 93d Cong., 2d Sess. (1974) (1974 House Rep.).

Second, in describing how the FOIA would operate, the comments of congressional committees and individual legislators consistently limited the scope of disclosure to documents in the government's custody and control. Thus, the committee reports observed that under FOIA "all [nonexempt] *materials of the Government* are to be made available" (Senate Rep. at 10; House Rep. at 11 (emphasis added)) and that the Act "would * * * provide a true Federal public records statute by requiring the availability * * * of all of the *executive branch records* * * *" (House Rep. at 1 (emphasis added)). Each request must contain a "reasonable description enabling the *Government employee* to locate the requested records" (Senate Rep. at 8; House Rep. at 9 (emphasis added)).²² Certain confidential data "*submitted* * * * to a lending agency," "*obtained by the Government,*" "*collected by Government agencies,*" or *filed with Federal agencies,*" otherwise subject to disclosure, were made exempt (Senate Rep. at 9; House Rep. at 10-11 (emphasis added)).

Individual comments by legislators and agencies echoed this understanding. Representative Moss, a sponsor of the FOIA, remarked that the law gave legal recognition to the public's "basic right to gain

²² Similarly, when Congress modified this provision in 1974, the House Report stated that "[a] 'description' of a requested document would be sufficient if it enabled a *professional employee of the agency* who was familiar with the subject area of the request to locate the record with a reasonable amount of effort." 1974 House Rep. at 6. See also 1974 Senate Report at 10, 24, 25.

access" to "official records" and "public records" 112 Cong. Rec. 13641-13642 (1966). Other legislators noted that under the FOIA records "of official government action [] are public property,"²³ that agencies must disclose "all their records" not exempted so that citizens would "have a right to obtain public records * * *,"²⁴ and that the Act concerned "public records."²⁵

Moreover, during the Senate hearings on the FOIA a representative of the Interstate Commerce Commission commented that "[s]ince the word 'records' * * * is not defined, we assume that it includes all papers which an agency preserves in the performance of its functions." *Administrative Procedure Act: Hearings on S. 1160, S. 1336, S. 1758, and S. 1879 Before the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 89th Cong., 1st Sess. 244 (1965) (1965 Senate Hearings).²⁶ The Comptroller General suggested that all documents produced under the FOIA should "remain" in the custody of the agency. *Id.* at 376. And at the close of the House hearings, Senator Ervin observed that in the final measure "every legitimate need for protection of any record or information *in the custody of departments or agencies* has been considered in

²³ 112 Cong. Rec. 13653 (1966) (Rep. Rumsfeld).

²⁴ 112 Cong. Rec. 13660 (1966) (Rep. Dwyer).

²⁵ 112 Cong. Rec. 13657 (1966) (Rep. Reid).

²⁶ This appears to be the only statement in the legislative history of the FOIA attempting to define the term "records" or "agency records."

the House and Senate measures." *Federal Public Records Law: Hearings on H.R. 5012 et al. Before a Subcomm. of the Comm. on Government Operations, 89th Cong., 1st Sess. 166 (1965) (1965 House Hearings)*.²⁷ Not once, so far as we are able to determine, is there a suggestion in any of the congressional hearings, reports, or floor debates that the Act might reach privately owned and possessed materials, regardless of the relationship between those materials and governmental functions.

This legislative silence speaks volumes. Both the House and Senate Committees asked all federal agencies to comment on the proposed FOIA, and many did. 1965 House Hearings at 203-276; 1965 Senate Hearings at 365-505. Almost without exception, federal agencies opposed mandatory disclosure of all non-exempt documents, chiefly on the grounds that mandatory disclosure would impose a huge administrative burden in view of the large number of agency records²⁸ and that depriving agencies of all discretion to withhold was unwise.²⁹ Agency opponents of the FOIA cited numerous examples of unreasonable dis-

²⁷ In keeping with this original understanding, a House oversight study in 1972 characterized the FOIA as a "promise of access to public records." H.R. Rep. No. 92-1419, 92d Cong., 2d Sess. 9 (1972).

²⁸ See, e.g., 1965 Senate Hearings at 204, 236, 244, 382, 483. Professor Davis suggested that the burden would be enormous but could be mitigated by giving agencies time to establish two records systems—one open to public perusal and one closed to the public. 1965 Senate Hearings at 147-158.

²⁹ See, e.g., 1965 Senate Hearings at 366, 376, 383, 402, 406, 416-419, 425, 436, 440, 445, 470, 489.

closures that would be required by the bill.³⁰ It is significant that none of these examples involved documents not in the custody and control of the federal government. Had it been imagined by anyone that the administrative burdens to be imposed by the Act would also extend to acquiring and producing documents in the private sector, even if limited to records of federal grantees or other private individuals or groups dealing with the government, the objections to the bill unquestionably would have multiplied. The "awesome implications" (App. 234) of disclosure of billions of private documents could not have gone unnoticed. Obviously, proponents and opponents of the FOIA alike assumed that the Act reached only the records in the possession and control of federal agencies.

Our discussion would not be fair if we did not acknowledge that the issue presented in this case was not a central focus of Congress in considering the FOIA. But we believe it is of immense probative value that the isolated comments that do appear in the legislative history consistently favor the view we espouse. Perhaps even more noteworthy, there is not a single comment in the legislative history to lend weight to petitioners' tortured reading of the Act. In sum, in the face of such silence concerning a bill as much debated as the FOIA, "[i]t would require the suspension of disbelief to ascribe to Congress the design to" require the release of records in private hands. *Brown v. GSA*, 425 U.S. 820, 833 (1976); see

³⁰ See, e.g., 1965 Senate Hearings at 196, 479.

Edmonds v. Cumpagnie Generale Transatlantique, No. 78-479 (June 27, 1979) slip op. 9-10.

C. The Structure Of The Act Reinforces The Conclusion Offered By Its Language And Legislative History

This Court has often looked to the complete structure of a statute to illuminate the meaning of its parts. *Train v. NRDC*, 421 U.S. 60, 86 (1975); *SEC v. Sloan*, 436 U.S. 103, 121 (1978); *Miller v. Youakim*, No. 77-742 (Feb. 22, 1979), slip op. 12-13; *Alexander v. HUD*, No. 77-874 (Apr. 17, 1979), slip op. 19; *So. Ry. Co. v. Seaboard Allied Milling Corp.*, No. 78-575 (June 11, 1979), slip op. 11. The structure of the FOIA reveals at virtually every turn an intent to reach only documents in the custody and control of a federal agency.

First, the term "agency records" gains content when viewed against the types of agency records exempted from disclosure. Section 552(b)(4), for example, exempts trade secrets and commercial or financial information "obtained from a person," without making any provision for the identical information in the possession of a federal grantee or other private party. Exemption 4 was meant to protect confidential information "submitted" by a borrower to a lending agency or "obtained by the Government" through questionnaires or other inquiries, where such information "would customarily not be released to the public by the person from whom it was obtained." Senate Rep. at 9; House Rep. at 10. That Congress found it necessary to exempt only such materials in the possession of an agency demonstrates that, a

priori, the Act has no application to similar documents in private hands, regardless of the connection between those documents and the agency's official functions. Until the agency has actually "obtained" the records, Exemption 4 (and, logically, the FOIA itself) are inapplicable.

By the same token, Section 552(b)(8) exempts certain reports "prepared * * * for the use of an agency responsible for the regulation or supervision of financial institutions." The Act does not exempt similar financial information prepared for the use of and held by the financial institutions themselves. Congress, however, clearly intended that such information would be made "available only to the Government agencies responsible for the regulation or supervision of such institutions" (Senate Rep. at 10; House Rep. at 11). Obviously, then, Congress did not intend the FOIA to reach those private documents.

The procedural provisions of the Act tell the same story. Agencies normally must decide within 10 days whether to comply with an FOIA request, but they may extend the time to 20 days where there is a need to consult with "another agency having a substantial interest in the determination of the request." 5 U.S.C. 552(a)(6)(B)(iii). See H.R. Conf. Rep. No. 93-1380, 93d Cong., 2d Sess. 11 (1974). Had Congress contemplated that documents owned and possessed by private parties were subject to disclosure, it undoubtedly would have allowed an extension of time for consultation with such private parties, not just with other federal agencies.

Similarly, Section 552(a)(4)(B) authorizes district courts to enjoin any "agency" from "withholding" records and places the "burden * * * on the agency to sustain its action." No provision is made for enjoining private individuals or groups from withholding their own records or for placing the burden on them to justify the refusal to release. Section 552(a)(4)(G) empowers the court to punish for contempt any responsible agency employee who violates an order to produce withheld documents, and Section 552(a)(4)(F) requires the Office of Special Counsel of the Merit Systems Protection Board to consider whether disciplinary action is warranted against any federal employee who, in the court's view, arbitrarily withholds agency records (see Civil Service Reform Act of 1978, Pub. L. No. 95-454, Section 202(a), 92 Stat. 1121, 1128, adding 5 U.S.C. 1206 (e)(1)(C)). No analogous authority is provided to punish private parties for similar acts. See generally 1974 Senate Rep. at 21-24; H.R. Conf. Rep. No. 93-1380, *supra*, 10. Again, had Congress intended the FOIA to reach documents in private hands, it surely would not have omitted parallel enforcement provisions designed to prevent non-government individuals from frustrating a disclosure order. The omission demonstrates quite clearly that Congress meant to limit the universe of records covered by the Act to those in the custody and control of a federal agency.

II. THE FOIA SHOULD NOT BE EXTENDED BY IMPLICATION TO REACH THE UGDP DOCUMENTS AT ISSUE IN THIS CASE

The FOIA would be a remarkable statute indeed if it required private parties to open their papers to the public at large. Petitioners do not urge such a broad reading of the Act; in any event, such a contention (in light of the evidence mentioned above) would be untenable. Rather, petitioners argue (Br. 23-25) that a "limited" extension of the Act to cover the UGDP raw patient data would further the policies of the FOIA because (i) HEW "participated" in the design of the UGDP study and funded it, (ii) the agency has a right of access to the pertinent data, and (iii) the agency has relied on the data in making regulatory decisions.³¹

There are two problems with petitioners' approach. First, unless the exception carved into the FOIA at petitioners' behest were to be confined to the UGDP documents alone, it would be difficult if not impossible to identify limiting criteria in order to prevent billions of other private documents from falling within the disclosure requirements of the Act. Petitioners have mentioned three factors that they believe make the private records in this case sufficiently "federal"

³¹ Actually, only the NIAMDD funded the UGDP project and reviewed the project design and only the FDA proposed to regulate oral hypoglycemic drugs. NIAMDD and FDA are the same agency only in the sense that they are both components of HEW, which is an "agency" under 5 U.S.C. 552(e). For purposes of argument, however, we assume that a single agency has performed the acts or has the powers set forth in petitioners' "congeries of considerations" (App. 230).

to mandate release under the statute. But some of these factors would apply equally to virtually every meaningful document in the hands of a private group receiving federal funds. While others would not, future requesters could identify additional factors, not present here, in order to "federalize" the private records to which they seek access under the Act.

Moreover, as we discuss in more detail below, the three factors on which petitioners rely, considered individually and collectively, do not warrant an extension of the FOIA to include the UGDP documents, which are not in the possession, custody or control of a federal agency.

A. Agency Funding And Review Of The UGDP Project

Petitioners contend (Br. 28-36) that HEW's funding and auditing of the UGDP project and its participation in the project's design transforms the UGDP data into "agency records." But, as we have already noted (see pages 20-23, *supra*), UGDP is not a federal agency within the meaning of the FOIA. Congress expressly elected not to subject recipients of federal funds to the disclosure requirements of the Act. The fact that UGDP has received federal funding, therefore, is immaterial to the question presented in this case.

Moreover, the agency's regulation of grantees does not make the relationship a "partnership" whose documents belong to the agency. No doubt, Congress could provide that all property acquired by federally financed projects belongs to the United States. It has not done so. To the contrary, the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-

224, Section 4, 92 Stat. 4, requires agencies to use "procurement contracts" when the "principal purpose of the instrument is the acquisition * * * of property or services for the direct benefit or use of the Federal Government * * *." In contrast, "grant agreements" must be used when money is given to a recipient "in order to accomplish a public purpose of support or stimulation authorized by Federal statute, rather than acquisition * * * of property or services * * *" (Section 5, 92 Stat. 4). Here, a grant was used because there was no intent to acquire property.³²

Indeed, the regulations governing the administration of HEW funding programs specifically provide that "title to real property, equipment, and supplies acquired under a grant or subgrant shall vest, upon acquisition, in the grantee or subgrantee respectively." 45 C.F.R. 74.133. The materials constituting the original UGDP patient records and related forms are "supplies" within the meaning of this provision. 45 C.F.R. 74.132.³³ To be sure, at the end of certain projects, HEW may require a grantee to transfer title to certain property to the agency. See 45 C.F.R. 74.135-74.136. That, however, has not happened here and will not under present regulations.³⁴ In short,

³² The specific UGDP grants do not retain for the government ownership of materials accumulated by the recipients.

³³ "Supplies" means "all tangible personal property other than equipment." "Personal property" means "property of any kind except real property." 45 C.F.R. 74.132.

³⁴ Section 7(b) of the Federal Grant and Cooperative Agreement Act empowers agencies to permit grantees who are "nonprofit institutions of higher education" or "nonprofit organizations" engaged in "scientific research," as here (see App. 220 n.3), to retain "title to equipment or other tangible

ownership of the data in question is now (and shall remain) in the UGDP. It is not "partnership" property.³⁵

That UGDP owns the data is no accident. It is the result of a conscious policy distinction between grants and procurement contracts. When the government

personal property purchased with such funds." 92 Stat. 5. 45 C.F.R. 74.135(c) implements this statute by providing that title to "supplies" in such cases will remain in the grantee.

³⁵ Petitioners assert (Br. 29) that under 45 C.F.R. 74.24 "[t]he public at large has its own rights of access to grantee records, which can be restricted only in special and limited circumstances." If that were so, this FOIA lawsuit would never have been necessary. It is not so, however. Section 74.24 only provides for access by "HEW and the Comptroller General of the United States, or any of their authorized representatives * * *." Section 74.25, which may have been the subject of petitioners' observation, likewise offers no aid to petitioners. It provides:

Unless required by Federal statutes, awarding parties may not impose grant or subgrant terms which limit public access to records covered by this subpart except after a determination by the granting agency that the records must be kept confidential and would have been excepted from disclosure under HEW's "Freedom of Information" regulation (Part 5 of this title) if the records had belonged to HEW. This section does not require recipients or their contractors and subcontractors to permit public access to their records.

This provision merely prohibits agencies or grantees from restraining a recipient or subgrantee who desires to allow public access to his records. It specifically disclaims any intent to require public access to the records. Finally, needless to say, the regulations cited by petitioners (Br. 29) governing public use of government-owned or financed inventions (45 C.F.R. 6.1, 8.0) have no applicability to the UGDP patient records.

wishes to buy services or goods, it uses a procurement contract, as directed by tradition and the 1977 Act. See Mason, *Current Trends In Federal Grant Law—Fiscal Year 1976*, 35 Fed. Bar. J. 163, 166-168 (1976); Staats, *Federal Research Grants*, 205 Science 18, 19 (July 6, 1979). When the government wishes to promote certain nongovernmental activity in order to promote the public interest, it uses a grant, as required by tradition and the 1977 Act. The grantee may use the funds of the grant as his own (within the terms of the grant), and the property he acquires during the grant is his own, subject only to whatever accounting must be made at the end of the project.

Nor does it matter that NIAMDD "participated" in the design of the UGDP project and monitored it for compliance. So far as the record discloses (see generally App. 145-148), NIAMDD did no more than would be expected of any federal agency in ensuring that a project run by private persons with federal funds was structured and implemented so as to be sufficiently in the public interest to deserve initial and continued funding.³⁶ As the court of appeals observed, there was no "significant government control of day-by-day operation [of the UGDP program], or detailed involvement in the planning or execution

³⁶ See *United States v. Orleans*, 425 U.S. 807, 815-816 (1976) (footnote omitted): "[B]illions of dollars of federal money are spent each year on projects performed by people and institutions which contract with the Government. These contractors act for and are paid by the United States. They are responsible to the United States for compliance with the specifications of a contract or grant, but they are largely free to select the means of its implementation."

of the program, [so] the overall concept of autonomy of grantees persists, even though there are federal objectives, right of federal audit and perhaps some over-arching federal requirements" (App. 237).

Finally, a rule requiring disclosure in these circumstances would impose new and serious burdens on acceptance of a federal grant. Grantees would be forced to accept the obligations not only to perform adequately and to comply with the various record-keeping, reporting and audit requirements that accompany a grant, but also to suffer disclosure to any member of the public of all documents related to the project funded by the grant if the "government participation" test is met. Organizations unwilling to subject their projects to such unlimited public scrutiny might well forego federal funding, with the consequent harm both to the private organization and to society in general (see App. 235-236).³⁷ Perhaps equally as troubling, federal agencies might be encouraged to reduce scrutiny of their grantees' projects in order to avoid a charge of "significant involvement in the study's planning, implementation, and monitoring" (see Pet. Br. 28). This, too, would obviously work to the detriment of the grantee and the public interest.³⁸

³⁷ This problem is discussed in more detail in the Brief of the American Council on Education, et al., as Amici Curiae.

³⁸ As petitioners frankly concede (Br. 30), "NIH could choose to establish a different type of partnership structure providing less (or more) grantee accountability or autonomy. Similarly, would-be grantees could decide that the benefits of

In sum, NIAMDD's funding, "participation" and regulation of the UGDP project do not overcome the undeniable fact that UGDP alone owns and possesses the raw patient data. Insofar as the FOIA is concerned, petitioners are no more entitled to inspect the UGDP records on account of the federal funding and "participation" than they would be to inspect data developed by similar private research programs receiving no federal assistance at all.

B. Agency Access To The Project Data

Petitioners argue (Br. 37-42) that HEW's right of access to private grantee records under its regulations establishes their right to the same records under the FOIA. There are a number of flaws in this reasoning. The first was noted by Judge Leventhal, writing for the court below: To the extent that language in these regulations, or in the UGDP grant itself, gives HEW a right of access to the UGDP records, "it indicates that these are not agency records prior to the exercise of that right" (App. 231).

Moreover, petitioners ignore the fact that NIAMDD's right of access is limited to specified regulatory purposes. 45 C.F.R. 74.24 authorizes the granting agency to inspect UGDP's records only "in order to make audit, examination, excerpts, and transcripts." 21 C.F.R. 312.1 authorizes the FDA to inspect the UGDP patient data only for reasons related to the investigational new drug exemptions

NIH funding are outweighed by the costs of NIH control and therefore decline involvement in the extramural program."

obtained by the private group. Neither of these provisions authorizes, much less requires, the agency to seek access to the data for the sole purpose of allowing the public at large to rummage through UGDP's records.

This problem may not be solved by requiring the agency to copy the 55 million documents and hold the copies for public inspection. Such a course would be a subterfuge without any more anchor in the agency's inspection authority than allowing the public to inspect the original data. In any event, imposition of that obligation on the agency would contravene the established principle that the FOIA does not require the government to generate records for the purpose of public disclosure. *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 161-162 (1975); *Renegotiation Board v. Grumman Aircraft Engineering Corp.*, 421 U.S. 168, 192 (1975); *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (1967).³⁹

Indeed, the suggestion that a federal agency's right of access to private documents for regulatory pur-

³⁹ A separate problem with petitioners' argument is that it would imply into the FOIA a private right of action to force an agency to exercise its option to obtain a record it does not but could possess. We have discussed this issue in the government's brief in *Kissinger v. Reporters Committee for Freedom of the Press*, Nos. 78-1088 and 78-1217 (pages 34-38). Here, the case for an implied private right of action is even weaker than in *Kissinger* because the authority creating the right of access is a regulation, not a statute, and is permissive, not mandatory.

poses somehow requires the agency to obtain the record in response to an FOIA request falls of its own weight. "Right of access" provisions are common in federal grants and contracts. See *Eli Lilly & Co. v. Staats*, 574 F.2d 904 (7th Cir.), cert. denied, No. 78-190 (Nov. 6, 1978). Beyond that, there is hardly a document in the United States that is not subject to subpoena, summons or civil investigative demand.⁴⁰ It is not an overstatement to say that federal agencies have a right of access to many documents in the hands of almost everyone who deals with the federal government, and almost everyone deals with the federal government. In short, the fact that a federal agency may have the right to inspect private documents for specified purposes related to the agency's statutory goals does not establish a derivative FOIA right of the public to do the same.

C. Agency Reliance On The UGDP Study

Petitioners' final contention (Br. 43-50) is that the data at issue in this case should be disclosable under the FOIA because the FDA has taken regulatory action based in part on the published results of the UGDP study. "[T]his absorption of the raw data into the regulatory process," petitioners assert,

⁴⁰ It is no answer to this argument to say that the government would never be required to subpoena a document solely for FOIA purposes because that would be a misuse of the subpoena power. It would be an identical misuse of the government's access rights under a regulation, contract, or grant for an agency to obtain records for the sole purpose of complying with an FOIA request.

"inextricably renders them 'agency records'" (*id.* at 43). But the fact that the agency may have relied on the reports and audits of the project does not transform the underlying patient data into "agency records." Even in its broadest cast, the purpose of the FOIA is to inform the public of the "decisions their government is making" and "the basis on which those decisions are being made." S. Rep. No. 93-854, 93d Cong., 2d Sess. 5 (1974). It does not create a right to know what even the government does not know.

Here, the decisions of the FDA concerning oral hypoglycemic drugs and the bases of those decisions—the reports and audits—have been fully disclosed to petitioners and the public (see page 13, note 13, *supra*). The agency informed petitioners on a number of occasions that "this Department does not now have and never has had any of the raw data on which the UGDP study was based" (App. 57). If the agency's decision not to review all 55 million UGDP documents was a mistake or an abuse of discretion, the full force of the FOIA has been spent in bringing that mistake to the public's attention. As the court of appeals noted (App. 226-227 n.11), the agency's substantive regulatory decision may be challenged "by well-established mechanisms independent of FOIA." See 5 U.S.C. 706; *Renegotiation Board v. Banner-craft Clothing Co.*, 415 U.S. 1, 24 (1974).

Petitioners' position in this regard is not enhanced by their extended explanation of why they need the original patient data (Br. 34-36, 50-52). Need is not a relevant factor under the Act. See Davis, *Adminis-*

trative Law Treatise § 3A.21 (1970 Supp.). The FOIA confers a right of access on the general public to all nonexempt agency records. The universe of documents comprehended by the Act is neither diminished nor enlarged by the reason the request is made. *NLRB v. Sears, Roebuck & Co.*, *supra*, 421 U.S. at 143 n.10. Hence, the fact that the UGDP "study is not replicable" (Pet. Br. 36) and that petitioners must receive the raw data if they are to validate or disprove the study's findings is entitled to no weight in this litigation. If petitioners' legal arguments are correct, then *any* requester would be equally entitled to inspect the records for any purpose or for no purpose at all.

Finally, petitioners' reading of the FOIA, if accepted, would severely hamper federal agencies, especially in the health area, by effectively requiring every agency that relies on a scientific study in taking agency action to acquire and make available the often voluminous underlying data used in the study. Agencies often rely on published medical and scientific studies in rulemaking and enjoy wide discretion in determining how much supporting data to obtain (see App. 227 n.12).⁴¹ Petitioners' interpretation of the Act would rob agencies of much of this discretion.

Indeed, petitioners' argument presumably would impose the same burden where the agency declines to

⁴¹ See *FCC v. Pottsville Broadcasting Co.*, 309 U.S. 134, 143 (1940); *Wisconsin v. FPC*, 373 U.S. 294, 313-314 (1963); *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 786 n.2, 791-792 (1969); *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524-525 (1978).

regulate. An agency may receive a study urging stricter regulation but may discount its methodology and significance in the face of professional criticisms and decide not to follow its conclusions. Under petitioners' analysis, the agency would be dutybound to obtain and make available the raw data of the study so that proponents of regulation could answer the critics. The government, in sum, would be prevented from relying on the vast wealth of professional findings in the public domain except in the most compelling cases where the need justified the trouble and expense of reviewing the underlying data.⁴² There

⁴² Even if petitioners' rule were limited to federally-funded projects, it would affect a large sector of public health research in the United States. Federal health research grants alone totalled approximately \$4 billion in fiscal year 1978. See Brief of the American Council on Education, et al. as Amici Curiae at 4. In the same year, the United States spent \$26 billion in research and development grants. *Id.* at 20. Government agencies currently fund approximately 16,000 research grants. *Id.* at 21.

The burden on the government of obtaining, copying, storing, and making available for disclosure raw data in cases like this one would be enormous. The UGDP study, involving approximately 1,000 patients and some 55 million documents as raw data, is not the largest such study ever undertaken by a private group with federal funding. For example, the Framingham Epidemiological Study of Cardiovascular Disease, funded by grants from the National Heart Institute, a component of NIH, has been underway since 1949 and involves over 5,000 patients. See, e.g., Gordan & Kannel, *Predisposition to Atherosclerosis in the Head, Heart and Legs; The Framingham Study*, 221 J.A.M.A. 661-666 (1972). The Coronary Drug Project, funded by the National Heart and Lung Institute, another component of NIH, has been underway since 1969 and involves over 8,000 patients being treated in 53

may well be strong arguments in favor of this change in agency decisionmaking, but those arguments should be adopted, if at all, as a matter of administrative law, not FOIA policy.

D. The Combination Of Factors Identified By Petitioners Does Not Justify Treatment Of The UGDP Data As Agency Records

The "congeries of considerations" (App. 230) offered by petitioners is even less compelling than its parts. To begin with, each factor still suffers in combination the same faults it suffers individually. More important, however, petitioners' argument, by predicating FOIA relief on an amalgam of variables, introduces a vague and unworkable test into the FOIA. Release of records not in the agency's possession and control would turn on the substantiality of the agency's "involvement" in the production of the records, the scope of its "access" rights, the degree of its "reliance" on the report prepared by use of the records, and perhaps even whether the records are "unique" or "non-replicable" (Pet. Br. 25). Depending on the force of these factors in each case, millions or even billions of private documents would be deemed "agency records." Such an amorphous test, "based

clinics. Unlike the UGDP, the inspiration for this study came from the Institute's Advisory Heart Council. *The Coronary Drug Project*, Circulation, Vol. XLVII, No. 3, (Supp. No. 1, March, 1973). The volume of raw data in these studies will far exceed that in the UGDP. Yet, these are only two of over 1,800 studies currently funded by NIH. Additional studies are funded by the Department of Energy, the Department of Labor and other federal agencies.

upon all of the circumstances of the given case" (Pet. Br. 27), flies in the face of the congressional intent to eliminate the "vague phrases" in the APA and to replace them with "workable standards for what records should and should not be open to public inspection." Senate Rep. at 5; House Rep. at 5-7. See pages 28-29, *supra*. Petitioners' elastic standards reintroduce the very evil Congress sought to avoid.

In addition, as noted earlier (see page 39), there is no principled way to limit the definition of "agency records" to the factors petitioners have relied on here. Petitioners have obviously focused on the particular indicia of federal agency involvement in or connection with the UGDP data in an effort to win *this* case. But the next case to raise the issue may involve slightly different indicia—for example, the experiments that led to the raw data may have been performed by a private group in a government-leased laboratory, or a grantee may have been hired by a federal agency following his study in order to advise the agency on his findings. A host of other possibilities could easily be imagined. Nothing in the FOIA or its legislative history gives any hint as to how the judiciary would tackle the problem of deciding how much weight to give to each of these factors.

Congress' plan to establish a bright line between what is and is not subject to disclosure is of substantial importance in the administration of the FOIA. The bright line adopted in the Act—that only documents in the custody and control of a federal agency are subject to disclosure—has worked well in

practice and is vitally important in the prompt and accurate processing of thousands of FOIA requests annually.⁴³ Expansion of this category of records by adopting the unfocused test proffered by petitioners would blur the line beyond all utility and generate inevitable litigation over the disclosure of countless numbers of documents in the private sector.⁴⁴

Petitioners' sole answer to this argument is that a "restrictive definition" of "agency records" would subvert the "spirit" (Br. 53) and "essence of the Act—freedom of information to the public" (*id.* at 56). But as the court of appeals pointed out, "[i]t is tautology to say that requiring disclosure of grantee records will promote the disclosure policies of FOIA. * * * [D]isclosure is not required by the statute unless those records are agency records. Congress struck a balance in fashioning the FOIA, which precludes the boundless pursuit of one policy goal, even a dominant policy, to the exclusion of all countervailing con-

⁴³ For example, we are informed that the FDA processes over 32,000 FOIA requests annually.

⁴⁴ Congress has frequently drawn a bright line, even at the cost of some theoretical compromise of policy, when it has been thought important to provide clear and definitive boundaries in order to avoid, among other things, needless litigation. See *FPC v. Southern California Edison Co.*, 376 U.S. 205, 215-216 (1964); *Ford Motor Co. v. NLRB*, No. 77-1806 (May 14, 1979) (Powell, J., concurring); cf. *NLRB v. Robbins Tire & Rubber Co.*, *supra*, 437 U.S. at 224 (sustaining a categorical refusal by the NLRB to produce under the FOIA witness statements in pending NLRB proceedings on the ground that in general such disclosure would interfere with Board proceedings even though in individual cases it might not).

siderations" (App. 233). There is no warrant in the language or background of the FOIA to extend its disclosure obligations to documents, such as the UGDP raw data, that are owned by a private organization and are not in the possession, custody or control of a federal agency. The Court should not take such a drastic step, with its wide-ranging implications, without the clearest indication of congressional intent. See *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 238 (1978).⁴⁵

⁴⁵ In fact, evidence of congressional intent at the time the FOIA was enacted points the other way (see pages 24 to 35, *supra*). In addition, bills that would have extended the FOIA to federal grantees have been introduced in each Congress since the 92d Congress but have never been reported out of committee. See H.R. 11013, 92d Cong., 1st Sess. (1969); H.R. 1291, 93d Cong., 1st Sess. (1973); H.R. 1205, 94th Cong., 1st Sess. (1975); H.R. 3207, 95th Cong., 1st Sess. (1977); H.R. 1465, 96th Cong., 1st Sess. (1979). See also 119 Cong. Rec. 1099 (1973) (remarks of Congressman Young concerning one such bill).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

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Respondents.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE
DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF RESPONDENT DR. CHRISTIAN R. KLIMT

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**BRIEF OF RESPONDENT
DR. CHRISTIAN R. KLIMT**

OPINIONS BELOW

The opinion of the United States Court of Appeals for the District of Columbia Circuit (A. 217-37), the concurring opinion of Judge MacKinnon (A. 238-39), and the dissenting opinion of Judge Bazelon (A. 240-57) are reported at 587 F.2d 1128, 1139, and 1140 (D.C. Cir. 1978). The order of the court of appeals denying rehearing (A. 258) and Judge Bazelon's statement explaining his vote for rehearing (A. 259) are reported at 587 F.2d at 1148. The order of the district court (A.

180-81) denying the petitioners' motion for summary judgment and granting the respondents' motions to dismiss is not reported.

JURISDICTION

The court of appeals entered judgment on July 11, 1978. On July 25 a timely petition for rehearing and in the alternative suggestion for rehearing in banc was filed (A. 261-68). On October 17, 1978, the court of appeals denied the petition for rehearing (A. 258-60) and the suggestion for rehearing in banc (Ct. App. R. 9). The petition for writ of certiorari was filed on January 15, 1979, and was granted on May 14, 1979. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1) (1976).

STATUTES INVOLVED

This case turns upon the interpretation of the Freedom of Information Act, 5 U.S.C. § 552 (1976), which is reproduced in the appendix to the petitioners' brief at 25a.

QUESTIONS PRESENTED

A continuing research study conducted by private and state medical schools and hospitals and funded by federal grants has collected raw data upon which it has based certain conclusions. The federal government has never controlled the research and has never owned, controlled, or possessed the raw data that the petitioners seek pursuant to the Freedom of Information Act. Accordingly, this case presents the following questions of the interpretation of the Act:

1. Does the federal government's funding of the study transform the private and state institutions into federal agencies or transform the raw data into "agency records" under the Act?

2. Must the federal government, in response to a request for records under the Act, exercise whatever

rights of access it may have to obtain private and state documents, such as the raw data of the medical schools and hospitals, and thereafter make them available?

3. Does the reliance by the federal government upon the published findings of the study and upon an audit of some of the raw data transform all of the data into "agency records" under the Act?

STATEMENT OF THE CASE

The petitioners seek reversal of the decision of the court of appeals affirming the judgment of the district court, which had dismissed the petitioners' request for the production of the raw data generated in a study conducted by the University Group Diabetes Program and funded by federal grants. The court of appeals held that the federal funding of the study, federal access to the raw data compiled by the University Group, and reliance upon the published findings of the study do not convert the raw data into "agency records" under the Freedom of Information Act, 5 U.S.C. § 552 (1976).

In June 1959, a number of private physicians and scientists conceived of the idea of a long-term prospective clinical study to determine whether the treatment of mild adult-onset diabetes with insulin or tolbutamide prevented, delayed, or alleviated the principal complications (retinopathy, cardiovascular disease, nephropathy, and neuropathy) of this disease (A. 96; D. Ct. R. 4, ex. 2 to affidavit of G. Donald Whedon at 5, 7, and 8). As a result of the efforts of these physicians and scientists, a number of private and state medical schools and hospitals formed the University Group Diabetes Program to perform the study. The University Group eventually grew to include twelve participating clinics and a coordinating center at the University of Maryland School of Medicine. Between 1959 and 1961, the principal investigators who were to conduct the study prepared and evaluated its design, methods, and

objectives. The clinical part of the study began in 1961 (A. 145-46), and 1,027 patients entered the study between 1961 and 1965 (A. 134, 146).

In each of the participating clinics, the investigators allocated on a random basis recently diagnosed cases of mild adult-onset diabetes to one of four treatment groups. These groups consisted of: (1) standard diet plus placebo tablets; (2) standard diet plus a fixed dose of tolbutamide; (3) standard diet plus a fixed insulin dose; and (4) standard diet plus insulin in varying amounts dosed to maintain normal blood sugar levels. In 1963 a fifth group of standard diet plus a fixed dose of phenformin was added (A. 146).

When a patient entered the study, the clinics made an initial evaluation of his or her health. Thereafter, the clinics performed quarterly examinations to determine the degree of control of the diabetes and the development, if any, of the complications of the disease (A. 97-98). The clinics forwarded the records of these examination results to the coordinating center. The coordinating center collected and computerized these results and subjected them to periodic statistical analyses. The treatment groups were compared for the number of deaths observed in each group and the proportion among each group developing one or more complications. In addition, the coordinating center was responsible for maintaining uniformity in the records and in the laboratory techniques employed. For example, whenever a patient died, the coordinating center would forward the patient's records to two or more specialists for examination. This was done to ensure the consistency and quality of the findings. These consulting specialists were unaware of the treatment that the patient was receiving (A. 97-99).

Each of the schools and hospitals in the University Group applied for and received separate research grants from the National Institute of Arthritis, Metabolism, and Digestive Diseases¹ (the "NIAMDD") of the National Institutes of Health to fund its participation in the study. The NIAMDD provided these funds as part of its responsibility to support research in the field of diabetes and without any specific regulatory objective in mind. In 1966 the NIAMDD renewed the grants to continue the study, and in 1971 the grants again came up for review. The National Advisory Arthritis and Metabolic Diseases Council recommended their approval and gave the study a rating of "high program relevance", which was in effect a direction to the staff of the NIAMDD to provide financial support for the study (A. 146-47).

The Food and Drug Administration (the "FDA") was not involved in the planning, inception, design, or conduct of the study. The raw data of the study, such as patient charts and forms, are the property of the participating schools and hospitals and the individual investigators. The NIAMDD does not own these data. Furthermore, it is not the normal practice of either the NIAMDD or the National Institutes of Health to require grantees to submit their data for review, and submission of raw data is extremely rare. In this case, the University group has not submitted any of the data to the NIAMDD (A. 146-48).

¹ The NIAMDD is one of a number of a research institutes that collectively form the National Institutes of Health, all of which are part of the Public Health Service. The Public Health Service is the operating agency within the Department of Health, Education, and Welfare principally engaged in providing health services, conducting and supporting health research, and providing state and local aid. The Food and Drug Administration is a separate agency within the department primarily responsible for regulating the manufacture, labeling, and distribution of drugs. See generally Reorg. Plan No. 3 of 1966, *reprinted in* 5 U.S.C. app., at 391-95 (1976) and in 80 Stat. 1610 (1966).

The participating clinics are responsible for managing the day-to-day operations of the study. Representatives of the NIAMDD reviewed the design, methods, and objectives of the study before it began the clinical phase, but it had no involvement in the clinical phase except to review the periodic reports submitted to it. Finally, no officer or employee of the NIAMDD or of the National Institutes of Health has ever seen or possessed any of the raw data. It is estimated that the raw data consists of millions of separate documents, possibly as many as 55,000,000 documents, and many contain information that identifies patients (A. 146-48).

At the annual meeting of the American Diabetes Association on June 14, 1970, the University Group presented some of the results of its continuing study. These results indicated that, among other things, the use of tolbutamide to control mild adult-onset diabetes was no more effective than diet alone in prolonging life and that it led to a greater death rate from cardiovascular disease than was found in the groups treated with diet alone, a fixed dosage of insulin, or a variable dosage of insulin. Later that year, the University Group published these results in the *Journal of the American Diabetes Association*. The University Group Diabetes Program, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, I & II*, 19 *Diabetes* 747 (Supp. 2, 1970) (A. 72). Both the American Diabetes Association and the American Medical Association's Council on Drugs supported the validity of the study (A. 72). Subsequently, the University Group published its findings that phenformin also generated a higher incidence of cardiovascular disease. Knatterud, Meinert, Klimt, Osborne, and Martin, *Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, IV, A Preliminary Report on Phenformin Results*, 217 *J.A.M.A.* 777 (1971); The

University Group Diabetes Program, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, V, Evaluation of Phenformin Therapy*, 24 *Diabetes* 65 (Supp. 1, 1975). From time to time, additional findings have been published. See, e.g., Knatterud, Klimt, Levin, Jacobson, and Goldner, *A Study of the Effects of Hypoglycemic Agents on Vascular Complications in Patients with Adult-Onset Diabetes, VII, Mortality and Selected Nonfatal Events with Insulin Treatment*, 240 *J.A.M.A.* 37 (1978).

The University Group study has been criticized (A. 12-13). Accordingly, to assess the scientific quality of the study, the Director of the National Institutes of Health, in 1972, invited the President of the Biometric Society, a private organization of scientists, to appoint a committee to consider the statistical aspects of the study (A. 144). This committee evaluated the methods used in the clinical study, reviewed the published criticisms of the study, interviewed both critics and supporters of the study, and made new analyses from some of the original data. 40 *Fed. Reg.* 28,587, 28,590 (1975). None of the data that the University Group made available to the committee was ever submitted to the NIAMDD or any other agency of the federal government, nor were they required to be submitted (A. 148). The committee commented on the major criticisms of the study and concluded that the study's evidence of harmfulness was moderately strong. 40 *Fed. Reg.* at 28,590. See also Committee for the Assessment of Biometric Aspects of Controlled Trials of Hypoglycemic Agents, *Report*, 231 *J.A.M.A.* 583, 599 (1975).

Before the report of the committee of the Biometric Society was published, counsel for the petitioners requested from the NIAMDD, the FDA, and the Department of Health, Education, and Welfare a copy of a draft of this report and also "access to the raw data

which was accorded to the biometric study" (A. 40, 42-43, 49). On January 27, 1975, G. Donald Whedon, Director of the NIAMDD, supplied to counsel for the petitioners the galley proof of the final version of the committee's report. In addition, Dr. Whedon explained that no one in the Department of Health, Education, and Welfare had ever possessed any of the raw data of the study (A. 54). On May 6, 1975, counsel for the petitioners renewed his request for access to the raw data (A. 55). Counsel also requested the research design and protocol for the study submitted to the NIAMDD and a statement detailing all budget appropriations, allocations, and expenditures for the study (A. 56). He subsequently made a detailed request for records in the NIAMDD's files relating to the grants to the University Group (A. 63-65).

In a series of subsequent correspondence, Theodore Cooper, Acting Assistant Secretary for Health, responded that the Department of Health, Education, and Welfare had never possessed any of the raw data on which the study was based (A. 57); that all of the grantees' working documents remained in their possession and were not considered in any way to be part of the grant files maintained at the National Institutes of Health; that the National Institutes of Health had no duty to request that a grantee submit data not required as part of the grant; that, because the raw data did not belong to the Department of Health, Education, and Welfare, the Freedom of Information Act did not apply to the material requested (D. Ct. R. 4, app. to ex. 1); that neither the grants to the University Group nor the contract with the Biometric Society required the submission of the raw data to the National Institutes of Health; that the raw data was at that time in the form of microfilm and was being stored in a Maryland bank vault; and that Dr. Cooper was informed that Dr. Klimt, the director of the coordinating center, believed that the

data are protected from disclosure under Maryland law (A. 68-69). Nevertheless, all records in the NIAMDD's files on the University Group's grants and study were released to counsel for the petitioners, with two deletions that they have not challenged (A. 66-67).

On September 30, 1975, the petitioners filed suit against the respondents, the Secretary of the Department of Health, Education, and Welfare, the Assistant Secretary for Health, the Commissioner of Food and Drugs, the Director of the NIAMDD, and Dr. Christian R. Klimt, Director of the Division of Clinical Investigation at the University of Maryland School of Medicine and director² of the coordinating center for the University Group (A. 1, 3-11). The petitioners sought an order directing the respondents to produce the raw data of the University Group study which respondents may have possessed or to which any of the respondents may have had a right of access. The petitioners also requested that the court issue a declaratory judgment that they were entitled to these records and permanently enjoin the respondents from refusing to produce them (A. 10). On October 31, Dr. Klimt filed a motion to dismiss and a motion to quash service of process, and on November 21, the federal respondents filed a motion to dismiss and in the alternative a motion for summary judgment. The petitioners responded on December 5 with a motion for summary judgment.

On February 5, 1976, the district court entered an order denying the petitioners' motion for summary judgment and granting the respondents' motions to dismiss. Considering the various motions and the entire

² In July 1978, Dr. Genell L. Knatterud, Deputy Director of the Division of Clinical Investigation, became the principal investigator for the coordinating center. Dr. Klimt, however, is a co-investigator, and he remains the Director of the Division of Clinical Investigation, Department of Epidemiology and Preventive Medicine of the University of Maryland School of Medicine.

record in the case, the court found that no official or employee of the Department of Health, Education, and Welfare, the National Institutes of Health, the NI-AMDD, or the FDA was then or had ever been in possession of the raw data of the University Group study, that the raw data were the property of the individual investigators and the coordinating center and remained in the possession, custody, and control of the coordinating center, that neither the individual investigators nor the coordinating center was an agency within the purview of the Freedom of Information Act, and that, consequently, the raw data were not agency records subject to disclosure under the Act (A. 180-81).

The petitioners appealed this order to the court of appeals on February 27, 1976. On July 11, 1978, the court issued its opinion and judgment affirming the district court's order. Relying on *United States v. Orleans*, 425 U.S. 807 (1976), the court held that persons or institutions that receive grants from the federal government do not on that account become government agencies. Further, citing *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1975), the court concluded that the Freedom of Information Act did not impose upon federal agencies the obligation to exercise whatever rights of access they may have to the raw data to obtain the raw data to which they have access and to supply them to the general public. The court held that the general public may only demand a record that a federal agency has created or has obtained in the course of doing its work. 587 F.2d at 1136. The court also concluded that the policy considerations presented by the petitioners did not authorize it to extend the Freedom of Information Act beyond the federal agencies and agency records to which it applies. Moreover, the court discussed the policy considerations for not applying the Act to the records of federal grantees, e.g.,

the importance of preserving the autonomy of private and state entities conducting research.

Judge MacKinnon authored a short concurring opinion. In this opinion, he stated: "The plain implication derived from the language of the statute is that it does apply to records which belong to the agency or are in its possession—that is, records which the agency has created or obtained." 587 F.2d at 1139. Judge MacKinnon rejected the approach of the dissent because under it the interpretation of the statute would turn upon what a federal judge considered a significant degree of federal involvement. 587 F.2d at 1140.

Judge Bazelon, dissenting, would have applied the Act to the University Group's raw data. In his view, the federal funding for the University Group, the government's right of access to the data, and the government's reliance upon the University Group's study established a significant degree of federal involvement with the raw data, and that therefore this federal involvement converted the data into agency records. 587 F.2d at 1140.³

³ The petitioners have presented to this Court numerous allegations of fact unsupported by any evidence in the record. The petitioners have done this in three ways. They have made bare assertions without citing any sources for these assertions. See, e.g., petitioners' brief at 4 (the amount of grants to the University Group); 12 (concerning petitioners' knowledge about an earlier draft of the report of the Biometric Society); 32 n.39 (concerning liaison officers to the University Group); 32-33 (concerning a policy advisory board); and 39 (details of the conduct of the FDA audit). The petitioners also cite documents and sources not in the record and not provided by the petitioners. See, e.g., petitioners' brief at 16 & n.17 (letter dated January 5, 1977 from Neil L. Chayet to J. Richard Crout, M.D.); 22 & n.30 (telegram from American Medical Association Executive Vice President James H. Sammons, M.D., February 2, 1979); 41 n.48 (letter from Dr. Christian R. Klimt to Dr. Crout, March 1, 1976); 53-54 (two memoranda of telephone conversations concerning the FDA audit and a letter from Dr. Crout to Dr. Klimt). Further, the petitioners have included in an appendix to their brief

SUMMARY OF ARGUMENT

The Freedom of Information Act, 5 U.S.C. § 552 (1976), first enacted by Public Law No. 89-554, 80 Stat. 383 (1966), provides that all federal executive agencies are to make available to any person agency records unless those records fall within one of nine exceptions. § 552(a)(3). The Act also provides a judicial remedy for any person who believes that the agency is improperly withholding "agency records". § 552(a)(4)(B). "Agency records" are those records made or received by any federal agency, that is, any documents and other similar material within the possession or day-to-day control of a federal agency.

The raw data that the petitioners seek are not the records of any federal agency. They are the property of the participating private and state medical schools and documents which are not in the record and have cited these documents at 16, 17 & n.18 and at 36 n.42).

Many of these putative facts concern events that preceded the petitioners' complaint or the district court's hearing on the parties' motions, and the petitioners could have introduced into the district court proceedings evidence supporting these allegations. The respondents then would have had an opportunity to review and question any of these allegations or to place them in their proper context. The respondent believes that the petitioners' attempt to bring these allegations before this Court now is improper. However, the respondent also believes that all of these allegations, as well as the allegations of facts not found in the record but recited in secondary sources cited by the petitioners, are essentially irrelevant, and they do not contradict the undisputed facts upon which the district court's order was based. Accordingly, the respondent will not attempt to refute these allegations.

The respondent does not mean to suggest by his silence on these matters that he accepts the accuracy of the allegations or the implications that can be derived from them. In fact, he rejects these allegations and the implications that the petitioners attempt to draw, and he urges that this Court do the same. Nevertheless, even if all of these allegations were true, the respondent believes that they would not change the outcome in this case.

hospitals that comprise the University Group. The University Group, and not any agency of the federal government, possesses the raw data and has day-to-day control over them. Because neither the University Group nor its participating institutions are federal executive agencies, the data are not agency records. Furthermore, federal funding of the University Group's study, federal access to the University Group's records, and federal reliance upon both the University Group's published findings and a limited audit of some of the data do not make the University Group or its participating schools and hospitals federal agencies, and they do not change the raw data into the records of any federal agency.

The application of the Act to "agency records" and the definitions of "agency" demonstrate that Congress did not intend the Act to apply to a private or state recipient of federal funds or to its records. Indeed, the legislative history of the 1974 amendments states that the definition of agency does not include entities that receive federal appropriations but that are not controlled by the federal government. The language of the Act and its legislative history is consistent with federal court decisions holding that the federal government does not control a private or state institution because it provides it with federal funds and that such institutions are not federal agencies. Consequently, federal funding does not make the records of such entities "agency records".

Congress' choice of words requiring an agency to "make available" the records in its possession or subject to its control and the crafting of a judicial remedy for the improper "withholding" of such records expresses its intent that agencies need not use whatever rights of access that they may have to the documents of private and state entities in order to comply with a request under the Act. This intent has been recognized

by the Attorney General's contemporaneous construction of the Act and by many courts, including this Court. Such right of access or even the exercise of the right does not amount to possession of records still in the hands of private or state entities or control over those entities or their records. Thus, this access does not transform the raw data into agency records.

Finally, that a federal agency may have relied upon both the published findings of the University Group's study and an audit of some of the raw data does not make the raw data "agency records". The University Group and its participating institutions have retained day-to-day control of their raw data. In relying upon published findings, the federal government did not obtain possession of the raw data, and in conducting a limited audit of some of the raw data, the federal government did not exercise control over the raw data or take such control away from the University Group.

Congress deliberately chose to apply the Act only to records in the possession or direct control of federal agencies. Those individuals and organizations that must deal with the federal government know that their records are not subject to the Act unless the federal government obtains possession of their records or exercises such control over them or their records as to make them, in effect, federal agencies. Petitioners' argument, however, would obliterate these expectations. If the petitioners were to prevail, then every individual and every private and state entity that receives federal funds or that is subject to federal audit, or every non-federal individual or body whose work product may be relied upon by the federal government would in effect become federal agencies, and their records would be

subject to access by any person. It is clear that Congress intended no such result.⁴

ARGUMENT

THE FREEDOM OF INFORMATION ACT APPLIES ONLY TO RECORDS IN THE POSSESSION OR DIRECT CONTROL OF FEDERAL EXECUTIVE AGENCIES.

The petitioners present to this Court a strained interpretation of the Freedom of Information Act. They argue that the federal "involvement" with the University Group makes the data of the University Group's private and state medical schools and hospitals "agency records" under the Act. This "involvement" consists of the funding by the NIAMDD of the University Group's research study, the NIAMDD's alleged right of access to all of the University Group's data, and the unquantified reliance by the FDA on the published findings of the study, the Biometric Society committee report, and the FDA's limited audit of the raw data. The respondent suggests, however, that the specific language of the Act, in the context of commonly understood conventions of language and principles of law, expresses the specific as well as the general intent

⁴ The issues in this case are distinct from those in *Kissinger v. Reporters Committee for Freedom of the Press*, No. 78-1088, and *Reporters Committee for Freedom of the Press v. Kissinger*, No. 78-1217 (U.S., cert. granted Apr. 16, 1979). Those cases involve the issues of whether transcripts of telephone conversations of former Secretary of State Henry A. Kissinger are personal notes not subject to the Freedom of Information Act or are agency records under the Act, and whether the district court has jurisdiction to compel an agency to obtain records not in its possession because it had physical possession of them at one time. In this case, the NIAMDD and the FDA never had physical possession of the raw data that the petitioners seek. Moreover, the raw data were created by nongovernmental scientists and physicians working at state and private institutions, unlike the transcripts in the *Kissinger* cases, which were created by a government official on government time with the use of government facilities.

that, notwithstanding any putative federal "involvement" with the University Group, the Act does not apply to the raw data that the petitioners seek.

The Act requires "each agency, upon any request for records," to "make the records" available. 5 U.S.C. § 552(a)(3) (1976). If the agency does not comply with the request, a court may enjoin the agency from withholding "agency records" and may order the production of "agency records improperly withheld". 5 U.S.C. § 552(a)(4)(B) (1976). Thus, the Act applies only to "agency records".

Although the Act does not contain a definition of "agency records", standard usage and commonly understood principles of the English language provide the meaning. "Agency records" means records of an agency. The records of an agency are the records that an agency creates, possesses, or directly controls.

This definition directly follows the earlier congressional definition of records in the Records Disposal Act of 1943, 57 Stat. 380 (1943). When Congress adopted the Freedom of Information Act, the Records Disposal Act contained the following definition of "records":

[T]he word "records" includes all books, papers, maps, photographs, or other documentary materials regardless of physical form or characteristics, *made or received* by an agency of the United States Government in pursuance of federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions,

procedures, operations or other activities of the Government or because of the informational value of data contained therein.

44 U.S.C. § 366 (1964) (emphasis added). This definition⁵ has been recodified with only insignificant changes in 44 U.S.C. § 3301 (1976).

In interpreting the Freedom of Information Act shortly after its passage, the Attorney General cited this definition of records and concluded that the Act refers "only to records in being and in the possession or control of an agency." *Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 23-24 (1967) [cited in this brief as *Attorney General's Memorandum*], reprinted in Subcomm. on Administrative Practice and Procedure, Senate Comm. on the Judiciary, *Freedom of Information Act Source Book*, S. Doc. No. 93-82, 93d Cong., 2d Sess. 194, 222 (1974) [cited in this brief as *Source Book*]. Although Congress has amended the Act three times, it has yet to question the Attorney General's reference to the definition of records in the Records Disposal Act of

⁵ Although this definition contains two elements, that is, whether the documents are (1) made or received by an agency and (2) preserved or appropriate for preservation by that agency, the important element for purposes of the Freedom of Information Act is the first. Government documents made or received by an agency that are not appropriate for preservation are "nonrecord materials". 41 C.F.R. § 101-11.401-3(d)(1978). See also brief for federal parties in *Kissinger v. Reporters Committee for Freedom of the Press*, No. 78-1088, and *Reporters Committee for Freedom of the Press v. Kissinger*, No. 78-1217, (U.S., cert. granted Apr. 16, 1979), at 39-42. In this case, the Court need not reach the question of whether "nonrecord materials" are "agency records" within the meaning of the Freedom of Information Act, because the raw data that the petitioners seek are not documents "made or received" by a federal agency.

1943 or to change his interpretation of the meaning of "agency records".⁶

Similarly, this Court has recognized the plain import of "agency records". In summarizing the salient features of the Act in *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 221 (1978), the Court stated that the Act "requires that records and material *in the possession of federal agencies* be made available on demand to any member of the general public" (emphasis added). See also *Nichols v. United States*, 460 F.2d 671, 673 (10th Cir.), cert. denied, 409 U.S. 966 (1972) (stating that the Act applies to "all records and information in agency possession"), aff'g *Nichols v. United States*, 325 F. Supp. 130, 137 (D. Kan. 1971) (holding that "the Court may not require production of records not in custody or control of an agency").

The University Group's raw data are not the records of the federal government or any federal agency. The raw data that the petitioners seek are not contained in the records of the NIAMDD, the FDA, or any other agency in the Department of Health, Education, and Welfare and were not created by any agency, officer, or employee of the department. They have never been in possession of any officer or employee of the department (A. 54, 57, 68, 69, 143, 147, 148). The raw data are the property of the individual investigators and the

⁶ See also Pub. L. No. 94-29, § 19, 89 Stat. 158 (1975), which amended the Securities Exchange Act of 1934, § 24, 15 U.S.C. § 78x (1976) (emphasis added), as follows:

(a) For purposes of section 552 of Title V, the term "records" includes all applications, statements, reports, contracts, correspondence, notices, and other documents filed with or otherwise obtained by the Commission pursuant to this chapter or otherwise.

The purpose of this amendment was to make all documents filed with the Commission agency records for purposes of the Act and to provide that the Act governed all requests for these documents. S. Rep. No. 94-75, 94th Cong., 1st Sess. 136-37 (1975), reprinted in [1975] U.S. Code Cong. & Ad. News 179, 313-14.

University Group and are not owned by any agency of the federal government (A. 147). The University Group has not submitted any raw data to the federal government (A. 148). The FDA performed a limited audit of some of the University Group data, see 43 Fed. Reg. 52,732 (1978), and any documents or records that the FDA collected or created in this audit have been turned over to the petitioners (A. 202). In addition, all other documents and records in the possession of the federal government (with two deletions not challenged by the petitioners) have been turned over to the petitioners (A. 143, 202).

Faced with these facts, the petitioners have constructed an argument that the raw data are agency records because various federal agencies have had some involvement with the University Group's study. However, this involvement—funding of the study and access to certain records of the University Group by the NIAMDD and reliance by the FDA upon published findings and a limited audit—cannot transform the raw data into agency records unless the federal government has possessed the raw data or has caused the University Group's participating medical schools and hospitals to become federal agencies. As the respondent demonstrates, the factors that the petitioners cite, either separately or in combination, do not produce such a transformation. See *Ciba-Geigy v. Mathews*, 428 F. Supp. 523 (S.D.N.Y. 1977), (rejecting identical arguments raised by Ciba-Geigy, a manufacturer of phenformin.)

I.

THE RECEIPT OF FEDERAL FUNDS DOES NOT MAKE THE UNIVERSITY GROUP AN AGENCY OR ITS RAW DATA AGENCY RECORDS.

When the Freedom of Information Act was first passed by Public Law No. 89-554, 80 Stat. 383 (1966), and codified as part of the United States Code by Public

Law No. 90-23, 81 Stat. 54 (1967), it did not contain a definition of "agency". Because the Act is an amendment to the original section 3 of the Administrative Procedure Act, the definition of "agency" in the Administrative Procedure Act applies to it. That definition states:

"[A]gency" means each authority of the Government or the United States, whether or not it is within or subject to review by another agency

5 U.S.C. § 551(1) (1976).

The federal courts have interpreted this definition of agency to mean any administrative unit of the federal government "with substantial independent authority in the exercise of specific functions". *Soucie v. David*, 448 F.2d 1067, 1073 (D.C. Cir. 1971) (holding that the Office of Science and Technology was an agency of the federal government and hence was subject to the Freedom of Information Act). It has also been interpreted to mean any federal entity with authority in law to make decisions. *Washington Research Project, Inc. v. Department of Health, Education and Welfare*, 504 F.2d 238, 248 (D.C. Cir. 1974) (holding that initial review groups consisting of non-governmental consultants are not agencies within the meaning of the Administrative Procedure Act and hence are not subject to the Act). See generally Freedman, *Administrative Procedure and the Control of Foreign Direct Investment*, 119 U. Pa. L. Rev. 1, 4-13 (1970).

Because certain federal entities, such as the United States Postal Service, attempted to avoid complying with the Act by claiming that they were not agencies within the meaning of the Administrative Procedure Act, Congress amended the Freedom of Information Act in 1974 to include a broader definition of "agency". Section 552(e) now states:

For purposes of this section, the term "agency" as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

As House Report No. 93-876 explained, "the definition of 'agency' has been expanded to include those entities which may not be considered agencies under § 551(1) of title 5, U.S. Code, but which perform governmental functions and control information of interest to the public." H.R. Rep. No. 93-876, 93d Cong., 1st Sess. 8, reprinted in [1974] U.S. Code Cong. and Ad. News 6267, 6274. Thus, in addition to entities in the executive branch of government which have authority to make decisions, the definition of "agency" also includes corporations which are subject to substantial federal control over their day-to-day operations. *Rocap v. Indiek*, 539 F.2d 174, 177, 180 (D.C. Cir. 1976) (holding that the Federal Home Loan Mortgage Corporation was an agency within the meaning of section 552(e)).

The University Group does not fall within any of these definitions of agency. It is not an establishment in the executive branch or an independent regulatory agency. It was not created by federal law or by any of the federal agencies. It has no authority to make decisions. It exercises no power of the federal government. It is not a government corporation or a government controlled corporation. It is subject to no more control by the federal government than many other private or state institutions.

The University Group consists of twelve private and state medical schools and hospitals and a coordinating center at the University of Maryland. The physicians and scientists at the various participating institutions,

and not any agency of the federal government, originated the continuing clinical study conducted by the University Group. The only involvement of any agency of the federal government in the study was the NIAMDD's reviewing the design, methods, and objectives of the study, granting research funds to the University Group, and reviewing periodic reports submitted by the University Group (A. 146). The FDA was not involved in its planning, inception, or design (A. 146). The University Group, and no agency of the federal government, had full responsibility for the management of its day-to-day operations (A. 147).

The sole function of the University Group has been to conduct a clinical research study. It has analyzed the data from the clinical study and from time to time has published its conclusions about that data. At no time has it purported to make any governmental decisions or to exercise any governmental authority. Nor has it ever considered itself an agency of the federal government. For these reasons, the University Group is not an agency of the federal government within the meaning of the Act. See *Lombardo v. Handler*, 397 F. Supp. 792, 802 (D.D.C. 1975), *aff'd mem.*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977) (holding that the National Academy of Sciences and its committee on motor vehicle emissions, private entities which contracted with the government to conduct studies, are not agencies within the meaning of the Act); *Ciba-Geigy Corp. v. Mathews*, 428 F. Supp. 523, 526-28 (S.D.N.Y. 1977) (holding that the University Group is not an agency within the meaning of the Act). See also *Kerr v. United States District Court for the Northern District of California*, 511 F.2d 192, 197 (9th Cir. 1975), *aff'd*, 426 U.S. 394 (1976) (holding that the California Adult Authority is not an agency subject to the Act).

That the University Group was funded completely by federal grants does no alter this conclusion. As

Conference Report No. 93-1200 on the 1974 amendments indicates, Congress did "not intend to include [in the definition of agency] corporations which receive appropriated funds but are neither chartered by the Federal Government nor controlled by it, such as the Corporation for Public Broadcasting." Conf. R. No. 93-1200, 93d Cong., 2d Sess. 14-15, *reprinted in* [1974] U.S. Code Cong. & Ad. News 6285, 6293. See also *Lombardo v. Handler*, 397 F. Supp. 792, 802 (D.D.C. 1975), *aff'd mem.*, 546 F.2d 1043 (D.C. Cir. 1976), *cert. denied*, 431 U.S. 932 (1977).

The language that Congress did use in defining an agency and the conclusion that a federal agency does not include a private or state recipient of federal funds that is not controlled by the federal government are consistent with a number of decisions of this Court and other federal courts. For example, this Court held in *United States v. Orleans*, 425 U.S. 807 (1976), that a community action agency funded under the Economic Opportunity Act of 1964 was not a federal instrumentality or agency for purposes of the Federal Tort Claims Act. In reaching its conclusion, the Court stated that the determinative question was not whether the community action agency received federal money and must comply with federal standards and regulations, but whether its day-to-day operations were supervised by the federal government. The Court noted that the federal government spent billions of dollars on projects performed by people and institutions under contracts with the federal government and that federal funding affected innumerable activities of local and state government and of private institutions. The Court stated, "It is inconceivable that Congress intended to have waiver of sovereign immunity follow congressional largesse and cover countless unidentifiable classes of 'beneficiaries'." 425 U.S. at 816. Finally, the Court observed that the federal government did not control the "detailed physical performance" of all the

programs and projects that it finances by gifts, grants, contracts, or loans. 425 U.S. at 816. *See also Maryland v. United States*, 381 U.S. 41 (1965) (holding that civilian caretakers of aircraft owned by the United States and assigned to the Maryland Air National Guard were state, not federal employees, even though the caretakers were paid from federal funds and were required to comply with federal standards); *Greenya v. George Washington University*, 512 F.2d 556, 559-62 (D.C. Cir. 1975) (holding that federal funding of a university without any federal involvement in the actual management of the funded program, and the existence of a contract between the university and the federal government to teach government employees at government facilities did not make the university a governmental agency subject to the first and fifth amendments to the United States Constitution); *Spark v. Catholic University of America*, 510 F.2d 1977 (D.C. Cir. 1975) (holding that the receipt of federal funds did not convert a private university into an agency of the federal government for purposes of federal question jurisdiction); *Wahba v. New York University*, 492 F.2d 96 (2d Cir. 1974) (holding that the receipt of federal funds by a university and by the chairman of the Biochemistry Department who was conducting a research project funded by the National Institutes of Health did not transform the university or the chairman into governmental actors for purposes of the first and fourteenth amendments to the United States Constitution).

There is nothing in the Act's legislative history to suggest that Congress intended the Act to apply to the recipients of federal grants. The Act did broaden the public's rights to obtain records of federal agencies so that the public may be informed about what its government is doing. *See generally* S. Rep. No. 813, 89th Cong., 1st Sess. 2-3, 5, 10 (1965), *reprinted in Source Book* 36, 37-38, 40, 45; H.R. Rep. No. 1497, 89th

Cong., 2d Sess. 1, 12 (1966), *reprinted in* [1966] U.S. Code Cong. & Ad. News 2418, 2429; 112 Cong. Rec. 13,641 (1966) (remarks of Rep. Moss). Nevertheless, all of the examples of the unwillingness of federal officials to make available even the most innocuous records (such as a telephone book) that led to the Act's passage involved records that were in the possession of a federal agency, not in the possession of a recipient of a federal grant. *See* H.R. Rep. No. 1497 at 4-5, [1966] U.S. Code Cong. & Ad. News at 2422-23; *Freedom of Information, Hearings on S. 1666 and S. 1663 (in part) before the Subcomm. on Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 88th Cong., 1st Sess. *passim* (1963) [cited in this brief as 1963 Senate Hearings]; *Federal Public Records Law, Hearings Before a Subcomm. of the House Comm. on Government Operations*, 89th Cong., 1st Sess. *passim* (1965) [cited in this brief as 1965 House Hearings]. Even after the Act took effect, Congress' focus remained upon providing access to government records and the reluctance of federal agencies to give up documents in their possession. *See Executive Privilege, Secrecy in Government, Freedom of Information, Hearings Before the Subcomm. on Intergovernmental Relations of the Senate Comm. on Governmental Operations and the Subcomms. on Separation of Powers and Administrative Practice and Procedure of the Senate Comm. on the Judiciary*, 93d Cong., 1st Sess. *passim* (1973) [cited in this brief as 1973 Senate Hearings].

It is reasonable to expect that, had Congress intended the Act to apply to private and state recipients of federal grants, it would have directed some attention to the significant implications of such an application, that is, the effect upon private and state institutions receiving federal grants and upon the federal government's program of supporting research through grants. In the context of research grants, such an application would conflict with one of the major principles of

academic freedom—that a scientist be free to investigate an area, to locate data, to interpret that data, and to decide whether and when to publish the results of his investigations without the fear of interference or harassment by outside agents. See generally Machlup, *On Some Misconceptions Concerning Academic Freedom*, 41 A.A.U.P. Bull. 753 (1955), reprinted in American Association of University Professors, *Academic Freedom and Tenure*, 177, 178 (L. Joughlin ed. 1967). See also Morris, *Academic Freedom and Loyalty Oaths*, 28 L. & Contemp. Prob. 487, 489-90 (1963). However, if the Act applied to a research grant recipient, any member of the public could require a private or state researcher to open up his files before he has finished gathering or analyzing his data or publishing his findings. Thus, his research efforts could be subjected to harassment, misappropriations, or premature disclosures by outside interests motivated by financial, emotional, or philosophical considerations.

This prospect also raises serious questions about the federal effort to support research. Prominent physicians and scientists may not be willing to accept federal grants for research if others with a particular financial or ideological stake in the subject matter of the research could have ready access to the research documents under the Act. Thus, a decision to apply the Act to recipients of research grants requires a careful weighing of the benefits and detriments to the conduct of scientific research in the United States and the role of the federal government in this research, as well as a thorough airing of the many conflicting interests attending these issues.

On a larger scale, the extension of the Act to recipients of federal grants raises issues of federalism, for the states receive a large number of grants totalling billions of dollars. Many states have their own acts requiring varying degrees of disclosure of state records.

Maryland, for example, has determined that a custodian of records, such as Dr. Klimt, may deny access to the specific details of research projects conducted by a state institution and shall deny access to hospital records relating to medical care and other medical information. Md. Ann. Code art. 76A, §§ 3(b)(iii) & 3(c)(vii) (1978). To the extent that the Maryland statute and other state statutes conflict with the Federal Freedom of Information Act, the application of the Federal Act to Maryland and other state agencies receiving federal grants would either make those agencies ineligible for grants or would abrogate the Maryland and other state statutes.

The proper forum for resolving these policy issues is, of course, Congress and not a court. If Congress had intended the Act to apply to federal grantees, then it would have addressed the policy questions. Certainly, Congress was aware of the tremendous amount of money it has appropriated for grant programs. In 1966, the year the Act was adopted, Congress appropriated approximately \$808 million to the National Institutes of Health for medical research, which included almost \$675 million in the form of grants and contracts for research at nonfederal institutions. U.S. Dep't of Health, Education, and Welfare, *Resources for Medical Research*, Report No. 10 at 9 (1967). For the fiscal year July 1, 1966-June 30, 1967, the federal government budgeted approximately one and one-half billion dollars for basic research at universities and colleges through grants and contracts. Bureau of the Budget, *Special Analyses of the United States Budget, 1967*, at 116-17. For that fiscal year, grants to state and local government totaled 14.5 billion dollars. *Id.* at 137.

Furthermore, during the hearings in 1972 on the operation of the Act, John F. Sherman, Deputy Director of the National Institutes of Health, described the mission of the National Institutes of Health in detail

and the mechanism by which the Institutes awarded research grants. Dr. Sherman advised the subcommittee that the National Institutes of Health planned expenditures in fiscal year 1972 of \$792 million for research grants and \$232 million for research and development contracts. Significantly, Dr. Sherman and the subcommittee were concerned not about information and records in the possession of the grantees or contractors but about the information submitted by the grantees and contractors to the Institutes, that is, whether that information in the possession of the Institutes should be subject to disclosure under the Act. *U.S. Government Information Policies and Practices, Hearings Before the Subcomm. on Foreign Operations and Government Information of the House Comm. on Government Operations*, 92d Cong., 2d Sess. (Part 9) 3617, 3627, 3629 (1972) [cited in this brief as *1972 House Hearings*].

Congress has not been reluctant to impose obligations and conditions upon the recipients of federal grants. It has by statute imposed requirements that grant recipients keep books and establish accounting systems and that they be subject to audits. *See, e.g.*, 42 U.S.C. § 295h-5 (1976) (grants concerning allied health professions, enacted in 1965); 42 U.S.C. § 2835 (1976) (grants relating to the prevention and treatment of alcohol abuse and alcoholism, enacted in 1970).

It has also subjected grant recipients to federal requirements on matters of social policy not related to handing out and accounting for grant money. For example, in 1964, Congress imposed upon all recipients of federal grants an obligation not to discriminate against any person on the basis of race, color, or national origin in the utilization of federal funds. 42 U.S.C. § 2000d (1976). In addition, one author has listed at least eighteen additional statutes imposing conditions, apart from the requirements of the statutes

creating the grant program, upon the expenditure of federal grant moneys. Madden, *Future Directions for Federal Assistance Programs: Lessons from Block Grants and Revenue Sharing*, 36 Fed. B.J. 107, 115 n.48 (1977). If Congress had wanted to extend the reach of the Act to records of grant recipients, it knew how to do so.

Consequently, the language of the Act, its legislative history, and the authorities that have interpreted and applied it require one conclusion. Because the federal government did not exercise day-to-day control over the activities of the private and state organizations comprising the University Group, the receipt of federal research grants by those organizations does not transform them into federal agencies subject to the Act or their records into agency records. These same considerations also lead to the conclusion that the NIAMDD's right of access to certain records or the FDA reliance upon the University Group's published findings and a limited audit do not transform these organizations into agencies or their records into agency records.

II.

THE FREEDOM OF INFORMATION ACT DOES NOT IMPOSE ANY AFFIRMATIVE OBLIGATION UPON FEDERAL AGENCIES TO OBTAIN DATA FROM PRIVATE OR STATE ENTITIES.

The Freedom of Information Act requires each agency, upon any request for its records, to "make the records promptly available to any person". 5 U.S.C. § 552(a)(3) (1976). By this language, Congress did not intend to enact an information retrieval system. Its goal was simply to require federal agencies and federal employees to provide the documents that they had in their possession to any person who requests those documents. *See* pages 16-17 and 24-25 above. Neither the language of the Act nor its legislative history suggests that a federal agency must exercise whatever

auditing rights it may have and must obtain documents from private or state entities in response to a request for records. In short, the words "to make . . . available" do not mean "to obtain from outside of the government and make available".

The enforcement provisions of the Act support this conclusion. Section 552(a)(4)(B) states:

On complaint, the district court of the United States . . . has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant.

"Withhold" means "to hold back", "to keep back or in one's possession". *Webster's New International Dictionary* 2941 (2d ed. 1953). If Congress had intended that federal agencies must acquire documents not in their possession in response to a request, Congress would not have limited the district court's power to (1) enjoining federal agencies from "keeping" agency records in their possession, and (2) ordering the production of records improperly kept in their possession.

The language that Congress chose accurately reflects its goal to make available to the public documents in the possession of federal agencies. None of the instances of agency reluctance to give access to agency records that motivated Congress to pass the Act involved a refusal by an agency to exercise its auditing powers and obtain documents not in its possession. See generally H.R. Rep. No. 1497 at 4-5 [1966], U.S. Code Cong. & Ad. News at 2422-23; 1963 *Senate Hearings passim*; 1965 *House Hearings passim*; 1972 *House Hearings passim*; 1973 *Senate Hearings passim*.

The Attorney General's interpretation of the Act recognizes this specific intent:

The requirement of this subsection [5 U.S.C. § 552(3)] imposes no obligation to compile or procure a record in response to a request.

Attorney General's Memorandum at 23-24, *Source Book* at 222-23. Similarly, this Court and other federal courts have given effect to this plain meaning of the Act. In *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 161-62 (1975), this Court stated:

The Act does not compel agencies to write opinions in cases in which they would not otherwise be required to do so. It only requires disclosure of certain documents which the law requires the agency to prepare or which the agency has decided for its own reasons to create.

See also *Nolen v. Rumsfeld*, 535 F.2d 890 (5th Cir. 1976), *cert. denied*, 429 U.S. 1104 (1977) (holding that the Act does not require a federal agency to produce missing records and that the United States Army complied with the Act when it made available all of the requested Army records that were extant); *Linker v. Hills*, 453 F. Supp. 556, 561 (S.D.N.Y. 1978) (holding that the Securities Exchange Commission diligently searched missing records and exhibited good faith in assuring that upon locating these records it would make them available and therefore its failure to produce the missing records was not an improper withholding under the Act); *Disabled Officers' Association v. Rumsfeld*, 428 F. Supp. 454, 459 (D.D.C. 1977) (holding that the Act obligates an agency only to produce nonexempt records which it presently has and hence the court should not order the Secretary of Defense to provide in the future the names and addresses of officers who will be retired with a disability).

Since the publication of the *Attorney General's Memorandum*, Congress has amended the Act three times. The two most recent amendments came after this Court's decision in *Sears*. Yet, Congress has not changed the Attorney General's interpretation or the holding of this Court in *Sears*. If Congress wished to change the plain import of the Act and the Attorney

General's and this Court's interpretation, then Congress would have done so.

Congress most likely did not extend the Act to the records of private or state entities that are subject to audit by the federal government because of the drastic impact that such action would have on private and state entities. There are few activities in today's society that are immune from federal auditing powers.⁷ In addition, the application of the Freedom of Information Act to private and state organizations subject to federal audit would abrogate many state public information policies as expressed in state statutes and would violate the reasonable expectations of many private persons and organizations that their records are not subject to disclosure to the world at large, but only to one or more particular federal agencies which will only exercise their auditing powers when they need to do so to carry out their functions. If Congress had intended the Act to have so broad a reach, it would at the very least have

⁷ The following statutes are merely an example of the federal government's broad powers to require that private and state entities keep records, to demand access to those records, and to acquire the records of private or state entities: I.R.C. § 7602, 26 U.S.C. § 7602 (1976) (any taxpayer or potential taxpayer); 42 U.S.C. §§ 7414, 7616 (1977) (any person who owns an emission source or is subject to the Clean Air Act or any recipient of assistance under that Act); 15 U.S.C. §§ 78q, 78u (1976) (any person subject to the Securities Exchange Act of 1934); 12 U.S.C. § 1906 (1976) (any person subject to the Credit Control Act); 20 U.S.C. § 584 (1976) (state education agency responsible for administering state plans under the National Defense Education Act of 1958); 20 U.S.C. § 1022 (1976) (institutions of higher education and other public and private nonprofit library institutions receiving grants for the acquisition of library resources); 21 U.S.C. §§ 355, 357 (1976) (persons engaged in manufacturing drugs or introducing drugs into interstate commerce); 33 U.S.C. §§ 1318, 1361 (1976) (the owner or operator of any point of discharge and any recipient of financial assistance under the Clean Water Act of 1977); and 29 U.S.C. § 657 (1976) (each employer subject to the Occupational Safety and Health Act of 1970).

considered the interests of these private and state entities before acting.

In the instant case, the NIAMDD has a right to audit certain records of the University Group. 45 C.F.R. § 74.24 (1978). The FDA did a limited audit of the data for 150 patients. 43 Fed. Reg. 52,732, 52,733 (1978). Any documents that the FDA created or obtained in the course of the audit have been turned over to the petitioners (A. 202). The purposes of the Act have been served well.

Because the Act imposes no obligation upon a federal agency to acquire records in response to a request for records and because the Act only applies to records in the possession or day-to-day control of a federal agency, the petitioners' argument fails. Neither the NIAMDD's putative right of access or the FDA's limited audit of some of the data amount to sufficient possession or control of the data to make the data agency records. Similarly, the right of access and a limited audit does not make the University Group's participating schools and hospitals federal agencies.⁸ The University Group created the data and it possesses and controls them. The federal government does not. The University Group controls its day-to-day activities. The federal government does not. Here, the data are not subject to the Act.

III.

RELIANCE BY THE FEDERAL GOVERNMENT UPON THE UNIVERSITY GROUP STUDY DOES NOT TRANSFORM THE RAW DATA OF THE STUDY INTO FEDERAL AGENCY RECORDS.

The petitioners argue that the FDA and the Secretary of Health, Education, and Welfare have brought the raw data of the University Group's study under the

⁸ There is nothing in the record or in the petitioners unsubstantiated allegations in their brief to suggest that the University Group has served as a data haven to subvert the Act.

Freedom of Information Act because in taking certain regulatory actions they have relied upon the published findings of the study, upon the published report of the committee of the Biometric Society, and upon the limited FDA audit of some of the data. They assert that this alleged reliance is tantamount to reliance upon the raw data and hence that the raw data have been absorbed into the regulatory process.

This argument founders for a number of reasons. In the first place, reliance upon published findings of a study is not reliance upon the unpublished raw data generated by that study. The published findings result from the efforts of the University Group's private and state investigators to analyze the data, to organize them in patterns that the investigators deem appropriate, and to draw conclusions from them. These findings cannot be equated with the raw data any more than a legal brief can be equated with all of the facts and legal authorities that a lawyer may gather in preparing the brief.⁹ Similarly, a limited audit of some of the data (*see* 43 Fed. Reg. 52,732, 52,733 (1978)) and reliance upon that data or upon the audit does not "absorb" all of the data into the FDA regulatory process. Accordingly, neither reliance upon published findings nor the FDA's limited audit of some of the data and its reliance upon that audit can reasonably be deemed to create possession of or control over all of the data. In short, neither the FDA nor any other agency of the federal government has ever obtained possession of the raw data or ever exercised day-to-day control over the data or the University Group. Therefore, they are not agency records.

⁹ The distinction between published findings and the data underlying those findings was specifically recognized by the Commissioner of Food and Drugs in the administrative proceedings for the withdrawal of approval of new drug

Moreover, even if reliance upon published findings and a limited audit were the same as reliance upon the raw data—or, even if the FDA were to inspect every one of the millions of documents in the University Group's possession and were to attempt to rely upon those documents for any regulatory action without acquiring them—the Act would still not apply to the raw data. Such inspection and reliance are not possession of the data and are not sufficient control over the data to make them agency records. FDA's attempt to rely upon the raw data as a basis for regulatory action may not be valid. That, however, is of no concern here.

It follows that the petitioners' reliance argument is in reality an argument that the federal government should have obtained all of the raw data. This of course raises the issue of whether the materials relied upon are substantial evidence upon which regulatory decisions may be based. For example, whether the published findings of the University Group's study and the other material relied upon by the Commissioner of Food and Drugs in proposing the relabeling for all oral hypoglycemic drugs, 40 Fed. Reg. 28,587 (1975), are sufficient to support the proposed relabeling is an issue which must be considered first by the Commissioner and second by any court to which the final decision of the Commissioner may be appealed. It is not an issue before this applications for phenformin hydrochloride. Proposal to Withdraw Approval of New Drug Applications for Phenformin Hydrochloride (FDA final decision Nov. 15, 1978), *reprinted in* 44 Fed. Reg. 20,967, 20,969 (1979). In his final order withdrawing such approval the Commissioner noted that the record in the withdrawal proceedings contained nearly 400 articles published in the medical literature, none of which were accompanied by the raw data upon which they were based. The Commissioner also observed that the University Group's study was relied upon in those proceedings in the same way as the other articles. Accordingly, the Commissioner did not accept the petitioners' assertions that the administrative law judge erred in admitting the University Group's study into evidence.

Court and it has never been an issue in this case. Indeed, in considering this issue, the court of appeals stated that its holding that the raw data are not agency records raised no implications about the petitioners' ability to obtain the data in the proceedings before the FDA. 587 F.2d at 1134.

The petitioners' argument that reliance makes private and state records federal agency records under the Act, aside from having no basis in the language of the Act, fails for another reason. This argument contradicts one of Congress' main goals in passing the Act: to establish clear and simple guidelines for determining what records are to be made available and to whom. Congress provided that "agency records" should be made available to "any person". These words replaced the elastic and uncertain standards in the original section 3 of the Administrative Procedure Act.¹⁰ That section contained such vague phrases as "matters of official record", "persons properly and directly concerned", and "confidential for good cause", which were difficult to apply and which federal agencies used as grounds for withholding federal documents. See S. Rep. No. 813 at 5, *Source Book* at 40; H.R. Rep. No. 1497 at 4-5, [1966] U.S. Code Cong. & Ad. News at 2422-23. The test put forth by the petitioners would inject into the interpretation of the Act an equally elastic and uncertain standard. There is no way to determine how much reliance would be necessary before this metamorphosis of private and state records into federal agency records happened. Moreover, this standard would

¹⁰ This section stated:

(c) Public Records. — Save as otherwise required by statute, matters of official record shall in accordance with published rule be made available to persons properly and directly concerned except information held confidential for good cause found.

Ch. 324, 60 Stat. 238 (1946), formerly codified in 5 U.S.C. § 1002 (1964).

inextricably entangle the interpretation of the Act with the collateral administrative proceedings in which the federal agency's reliance occurred.¹¹

Finally, the reliance test is inappropriate because it attempts to incorporate into the Act consideration of the need for records as a criterion for determining whether those records are "agency records". The petitioners allege a tremendous need for acquiring the raw data. Petitioners' brief at 28, 52. This putative need derives solely from the reliance by the FDA and the Secretary of Health, Education, and Welfare upon the published findings of the University Group study. The petitioners in effect argue that, when the government relies upon the published findings of a study, or a portion of the raw data generated in the study—that is, when the government creates a perceived need in certain persons for all of the data—then all of the data become "agency records" under the Act, even though those data are the records of private and state entities. On the other hand, under the petitioners' argument, if there is no reliance and hence no need, then those private or state records do not become agency records.

¹¹ The difficulty in applying such a test is illustrated by the administrative proceedings for the suspension and withdrawal of approval of new drug applications for phenformin. On July 25, 1975, the Secretary of Health, Education, and Welfare suspended the approval of new drug applications for phenformin because the drug posed an imminent health hazard. The Secretary based this decision upon reports to the FDA of deaths due to lactic acidosis, data submitted by drug companies and hospitals, reports from other countries, and the published findings of the University Group study. Order of the Secretary Suspending Approval of New Drug Applications for Phenformin, NDA 11-624, 12-752, 17-126, 17-127, (DHEW July 25, 1977).

At the same time, the FDA began the hearings on the permanent withdrawal of approval of the new drug applications. 42 Fed. Reg. 40,959 (1977). After the hearings, the administrative law judge issued an initial decision, in which he ruled that the University Group's study could not be substantial evidence in the proceedings but could form the

It is clear that Congress did not intend this result. The Act eliminated the requirement that the person requesting documents demonstrate a need for those documents. See S. Rep. No. 813 at 5, *Source Book* at 40; *NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132, 143 n.10 (1975); *Environmental Protection Agency v. Mink*, 410 U.S. 73, 86 (1973); *Columbia Packing Co. v. United States Department of Agriculture*, 563 F.2d 495, 499 (1st Cir. 1977); *Robles v. Environmental Protection Agency*, 484 F.2d 843, 847 (4th Cir. 1973). The need for documents arising out of regulatory proceedings is similarly irrelevant. The Act was intended to be a disclosure statute, not a discovery statute. *NLRB v. Sears*, 421 U.S. at 143 n.10; e.g.; *Renegotiation Board v. Bannerkraft Clothing Co.*, 415 U.S. 1, 24 (1974); *Columbia Packing Co. v. United States Department of Agriculture*, 563 F.2d at 499, 500.

Consequently, whether and to what extent the federal government has relied upon the published findings of the University Group does not alter the plain import of the language of the Act. A person may obtain "agency records". "Agency records" are the records that an agency has created or acquired or that it possesses. Just as federal funding of the study that generated the

basis for expert testimony and for consideration of the safety of phenformin. Proposal to Withdraw Approval of the New Drug Applications for Phenformin Hydrochloride, Docket No. 77N-0150, (FDA initial decision Feb. 8, 1978), reprinted in 44 Fed. Reg. 20,977, 20,979 (1979). The Commissioner of Food and Drugs adopted this decision with some modifications. Proposal to Withdraw Approval of New Drug Applications for Phenformin Hydrochloride (FDA final decision Nov. 15, 1978), reprinted in 44 Fed. Reg. 20,967 (1979). In doing so, the Commissioner stated that he did not consider the University Group's study in reaching his final decision and that he was not adopting the references to the study in the substantive portions of the initial decision. 44 Fed. Reg. at 20,979. See also 44 Fed. Reg. 20,966, 20,966-67 (1979) (denial of petition of reconsideration of final order). Thus, the FDA's reliance upon the published findings of the University Group has varied from some reliance to no reliance.

records or federal access to the records is not equivalent to possession of the records or control over the University Group sufficient to make it a federal agency, federal reliance—by itself or in conjunction with federal funding and federal access—is not possession of the data or control over the University Group. The raw data that petitioners seek are not agency records.

CONCLUSION

For these reasons, the respondent requests that this Court affirm the judgment of the court of appeals and hold that the raw data generated by private and state institutions that conduct a research project funded by federal grants are not agency records within the meaning of the Act and that the Act does not impose an obligation upon federal agencies to acquire these private or state records simply because the federal government may have access to them or may have relied upon published reports based on them.

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IN THE
Supreme Court of the United States
OCTOBER TERM, 1978

No. 1118

PETER H. FORSHAM, Et Al.,
Plaintiffs-Petitioners,

v.

JOSEPH A. CALIFANO, JR., Et Al.,
Defendants-Respondents.

On Writ of Certiorari to the United States Court of Appeals
For the District of Columbia Circuit

**BRIEF OF THE AMERICAN COUNCIL ON
EDUCATION, ASSOCIATION OF AMERICAN
MEDICAL COLLEGES, ET AL. AS AMICI CURIAE
IN SUPPORT OF DEFENDANTS-RESPONDENTS**

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Plaintiffs-Petitioners,

v.

JOSEPH A. CALIFANO, JR., Et Al.,
Defendants-Respondents.

On Writ of Certiorari to the United States Court of Appeals
For the District of Columbia Circuit

**BRIEF OF THE AMERICAN COUNCIL ON
EDUCATION, ASSOCIATION OF AMERICAN
MEDICAL COLLEGES, ET AL. AS AMICI CURIAE
IN SUPPORT OF DEFENDANTS-RESPONDENTS**

INTRODUCTION AND LIST OF AMICI CURIAE

The amici curiae in this case include the American Council on Education, which is a nonprofit corporation organized under the laws of, and located in, the District of Columbia. Founded in 1918, the Council is a

membership organization of 1355 nonprofit institutions of higher education and 180 educational associations. The Council is the major coordinating body in post-secondary education.

The Association of American Medical Colleges is a voluntary, nonprofit, non-governmental corporation established under the laws of the State of Illinois, having its principal place of business in the District of Columbia. Its corporate purpose is the advancement of medical education. Its institutional membership includes all one hundred twenty four accredited and operating nonprofit medical schools and medical colleges in the United States. Its membership also includes over 400 teaching hospitals in which undergraduate and graduate medical education is conducted, and 63 academic and professional societies, the members of which are actively engaged in medical education and the conduct of biomedical research.

Also included as an amicus curia is the National Association of State Universities and Land Grant Colleges.

We respectfully refer the Court to the Statement of Jurisdiction, Citation of Opinions Below, Statement of the Case and the Statutes Involved presented in the brief of Plaintiffs-Petitioners.

CONSENT OF PARTIES

This amici curiae brief is being filed with the consent of all parties to this proceeding. Letters of consent of all parties have been filed with the Clerk of Court.

QUESTION PRESENTED

Are raw research data in the possession of a grantee of Federal research funds, including all records of basic research information and notes developed in the course of a research project but not included in required research reports, Federal agency records requiring disclosure to the public under the Freedom of Information Act?

INTEREST OF AMICI CURIAE

The amici curiae are associations of colleges, universities, and university officials with a substantial interest in Federally sponsored research. In 1978, America's universities performed 54% of all basic research undertaken pursuant to Federal grants. Staats, *Federal Research Grants*, "Science", Vol. 205, July 6, 1979, p. 18. A total of 58% of all research supported by the National Institutes of Health ("NIH") in fiscal year 1978 was performed by institutions of higher education. "Basic Data Relating to the National Institutes of Health", U.S. Department of Health, Education & Welfare, 1979, p. 3 (hereinafter referred to as "Basic Data Relating to the NIH"). In the performance of basic and applied research, the research investigators who conduct such research for institutions of higher education maintain records of various types of all research data and of observations with respect to such data throughout the research project. Such records are voluminous. Reports and other forms of publication which result from the research project do not encompass all of the records of information, data and observations. Such information, data and observations are referred to as raw data as opposed to the data which are reported and published after being interpreted and

analyzed. The amici curiae believe that a decision by this Court in favor of Petitioners resulting in the disclosure of such raw data would have a serious and adverse impact on the capacity of colleges and universities to undertake research supported by the Federal Government.

ARGUMENT

1. The Federal Research Grant Is A Method of Supporting Research Involving Autonomy of Grantees

Research activity by the Federal Government has grown enormously in the past 30 years. In the area of health research, involving mainly basic biomedical research and clinical medical research, Federal expenditures have grown from about \$74 million in fiscal year ("FY") 1950 to about \$4 billion in FY 1978. "Basic Data Relating to the NIH", U.S. Department of Health, Education & Welfare, 1974, p. 5; "Basic Data Relating to the NIH", *supra*, 1979, p. 5. Research expenditures in the military and space fields are higher than in the health area though the growth rate has not accelerated as it has in the area of health research. "Special Analyses, Budget of the United States Government, Fiscal Year 1980", p. 295. Most research activity in the health field has been conducted through the provision of financial assistance to institutions of higher learning by Federal grants. "Basic Data Relating to the NIH", *supra*, 1979, pp. 5, 26.

The use of Federal grants to support research is the only way a major national undertaking in basic and applied science related to the health of Americans is possible for it enables the Government to utilize the abilities of the many scientists not in the employ of the Federal Government.

In the opinion of the Circuit Court of Appeals in this case, the importance of autonomy for the non-Federal research institutions and investigators and the value of the grant form of assistance in fostering such autonomy are emphasized. The Court's majority makes the following observations:

"In a grant program the federal government gets the advantage of services rendered by someone who is doing his own thing, his own autonomous thing. It is not the same as a government operation in disguise.

"Through its grant to university groups, the government obtains the efforts of creative persons who flourish in an academic atmosphere. Such arrangements provide a measure of detachment and independence from the mission of the government agency. The researchers may feel the tug of government purse strings, but they also feel answerable to the standards of their academic colleagues.

...
 "The central question is whether the government is really involved in the core of the program. At least in a case such as the one before us, where there was no claim of significant government control of day-by-day operation, or detailed involvement in the planning or execution of the program, the overall concept of autonomy of grantees persists, even though there are federal objectives, rights of federal audit and perhaps some overarching federal requirements."

Forsham v. Califano, 587 F.2d 1128 (Circuit Court of Appeals, D.C. Circuit, 1978).

The grant device is one in which the grantee, a non-Federal institution, is helped "in an undertaking of his own, which the government aids because of a gen-

eral approval of the undertaking". Mason, *Current Trends in Federal Grant Law—Fiscal Year 1976*, 35 "Fed. Bar Journal", pp. 163, 166. "The grant is dominated by the grantees goal and his autonomy." Mason, *supra*, p. 167. The role of the Government in such an arrangement "can be likened to that of an interested and concerned donor . . ." Willcox, 22 Admin. L. Rev. 125 (1970). As the Circuit Court of Appeals for the Second Circuit reasoned in *Washba v. N.Y.U.*, 492 F.2d 96 (Court of Appeals for the Second Circuit, 1974), at page 102:

"This kind of arrangement whereby federal funds are used to prime the pump of research efforts in private scientific institutions which the government could not perform as well has social values too obvious to require elaboration. Only rarely are professors of Dr. Ochoa's eminence willing to enter government in peacetime. It is equally clear that scientists of his reputation on staffs of private institutions with a wealth of choices before them are not likely to be willing to undertake projects under public grants if they are deprived of the freedom of management which they consider necessary and would have in grants not federally financed."

In a recent article in "Science", the Comptroller General of the United States echoed these same sentiments about the need for the autonomy of researchers and grantee institutions. Staats, *Federal Research Grants*, "Science", Vol. 205, July 6, 1979, p. 18. In describing the individual grant supported researcher, he states that:

"He is his own director, his own boss. He has a heightened sense of self-reliance and autonomy, and this serves as crucial motivation for his work

. . . . Such autonomy has come to be viewed by many scientists, and non-scientists, as necessary to scientific excellence." Staats, *supra*, p. 19.

This article indicates the important role that Federal research grant support has played in fostering such autonomy and excellence. The purpose of grant support is characterized as follows:

"I would like to emphasize the basic intention of a research grant is to support, not to procure in the sense that one procures hardware. It inherently involves a long-term view, in that it supports and encourages effort which is characterized by its perennial and unspecific potential for social benefits, not by its ability to generate specific products or services." *Ibid.*

The autonomy of research grantees is also demonstrated by the affidavit in this case of Dr. G. Donald Wheldon, Director of the National Institute of Arthritis, Metabolism and Digestive Diseases ("NIAMDD") which financed the research involved in this case by grants. The pertinent parts of that affidavit are set forth in *Forsham v. Califano*, 587 F.2d 1128 (Circuit Court of Appeals D.C. Circuit, 1978), at p. 1131:

"The UGDP raw data (e.g. patient charts and forms) are the property of the individual investigators and the Coordinating Center and are not owned by NIAMDD Management of the day to day operations of grant supported activities is the responsibility of the grantee."

In this connection, see 45 C.F.R. §§ 74.80, 74.82.

In 1977 and 1978 the House and Senate passed the Federal Grant and Cooperative Agreement Act of 1977 which became law on February 3, 1978. 41 U.S.C. §§ 501

to 509. The intent of that legislation was to establish for Federal agencies statutory definitions and standards related to the use of grant, contract and cooperative agreements as methods of providing Federal funds to carry out Federal objectives. 41 U.S.C. § 501, Senate Report No. 95-449 (Government Affairs Committee), September 22, 1977, p. 2. 41 U.S.C. § 504 provides that a grant agreement shall be used whenever (1) the purpose is to transfer money or other Federal property or services to recipients in order to accomplish a public purpose of support or stimulation authorized by statute rather than the acquisition of property or services and (2) no substantial involvement is anticipated between the Federal agency and the recipient. While this provision was enacted in 1978, the legislative history indicates an intent to characterize "existing relationships" between the Federal Government and recipients. Senate Report No. 95-449, *supra*, p. 10. The Senate Report, *supra*, at page 31, makes it clear that the definition of a grant used was intended to embody concepts which had been used in the Federal Government since 1958:

"Second, the committee examined the House and Senate committee reports accompanying the bill which became Public Law 85-934, the Grants Act. (S. Rept. No. 2044, July 30, 1958 and H. Rept. 2640, August 15, 1958). Both reports relied upon an explanation of the legislation submitted by the Director of the National Science Foundation in expressing legislative intent. The following advantage of the grant over the contract is cited:

"Where the Government desires to engage the services of an educational or nonprofit organization for the conduct of a specific piece of research directed toward a specific problem,

the use of the contract form is obviously in order. On the other hand, where it is the desire of the Government to stipulate and support fundamental research in a given field, with the perimeters of inquiry limited only to the curiosity and creativity of the scientific investigator, the use of the grant form has several marked advantages.

"The committee feels that the legislative intent of the Grants Act was to provide authority for grants in instances wherein the basic relationship established was one of Federal assistance. This intent is compatible with the provisions of S. 1437."

The characterization of the grant agreement in 41 U.S.C. § 504 is certainly consistent with the grant relationship described by Willcox writing in 1970, and by Department of Health, Education & Welfare regulations and grants policy statements effective during the time of the transactions involved in this case. 42 C.F.R. § 52.10; 45 C.F.R. §§ 74.80, 74.82; "Public Health Service Grants Policy Statement", Department of Health, Education & Welfare, October 1974, pp. 33, 56, 57. See the succeeding section of this brief regarding a specific discussion of these regulations and policies.

The Federal Grant and Cooperative Agreement Act of 1977 adds additional weight to the proposition that the grant is intended to optimize grantee autonomy in carrying out research activity and is not intended to procure records of raw data collected in the course of research.

A holding in this case that the raw data involved in the UGDP research projects, and not in the possession of the Government, is subject to disclosure to the public would jeopardize the autonomy of all research grant-

ees and serve to make the major instrument of health research—the grant—much less effective. For reasons stated more fully hereafter, individual investigators and educational institutions would find participation in research undertakings far less attractive if records of basic research data were held to be agency records and subject to public disclosure.

2. HEW Regulations and Policies Reflect No Requirement That Grantees Make Basic or Raw Data Available to the Public

The basic premise of a Federal research grant then is that it is support for activities of the grantee that are consistent with a Federal research policy and that assure maximum autonomy to the grantee and investigators in undertaking that activity. Staats, *Federal Research Grants*, "Science," Vol. 205, July 6, 1979, pp. 18, 19; Mason, *Current Trends in Federal Grant Law—Fiscal Year 1976*, 35 Fed. Bar Journal, (1976), pp. 163, 166; *Washba v. N.Y.U.*, 492 F.2d 96 (Court of Appeals for the Second Circuit, 1974); 41 U.S.C. § 504. The Department of Health, Education & Welfare regulations and policy statements on grants are fully consistent with this premise and do not in any way require that the basic research data which underlies research publications and reports supported by Federal grants be treated as agency records. The regulations regarding research grants financed by the Department of Health, Education & Welfare do not require that basic research data be supplied to the Department. 42 C.F.R. § 52.10 establishes that the research grant is to assist in meeting the costs of conducting identifiable research activity, not to procure research data. Progress reports are required during and at the termination of research projects. 42 C.F.R. § 52(a) 12; 45 C.F.R. §§ 74.80, 74.82.

Interim and termination reports are essentially intended to produce a "summary statement of progress toward the achievement of the originally stated aims, a list of the results considered significant, and a list of publications resulting from the project . . .". "Public Health Service Grants Policy Statement", U.S. Department of Health, Education & Welfare, October 1, 1974, p. 33; "Public Health Service Grants Policy Statement", U.S. Department of Health, Education & Welfare, October 1, 1976, p. 42. Obviously, the reports are not intended to produce the basic research data accumulated during the project; even the results that have to be described are limited to those the scientist deems significant.

Plaintiffs-Petitioners argue that 45 C.F.R. § 74.24 gives the Government rights to the basic research data of research projects supported by grants and the dissent in the Circuit Court of Appeals in this case relies on that section of the regulations also. 45 C.F.R. § 74.24 provides in pertinent part that the Department of Health, Education & Welfare shall have the right of access to any books, or other records pertinent to the grant "in order to make audit, examination, excerpts, and transcripts". The limitation on access related to the purpose for which the information is gathered is explained in the "Public Health Service Grants Policy Statement", *supra*, October 1, 1974, p. 60; "Public Health Service Grants Policy Statement", *supra*, October 1, 1976, p. 77, as follows:

"An audit is made to:

- "1. Verify financial transactions and to determine whether grant funds were used in accordance with applicable laws, regulations, and procedures.

- "2. Provide the Government and the management of the grantee institution with objective appraisals of financial, accounting system, and administrative controls.
- "3. Determine reliability of financial records and reports."

Clearly, the intention of the regulations is to permit access only to records dealing with the financial and administrative aspects of the grant, not to the scientific data and findings of the research program itself. This point is reinforced by the sections in the "Public Health Service Grants Policy Statement" which explain to grantees what records must be released to the public. "Public Health Service Grants Policy Statement", *supra*, October 1, 1974, pp. 56, 57; "Public Health Service Grants Policy Statement", *supra*, October 1, 1976, p. 77. Those sections list for guidance as discloseable documents only the notice of grant award, the application if an award was made, interim and terminal progress reports, expenditure reports and reports of audits or surveys of grantee performance. Records of basic research data are clearly noticeable by their absence. Even interim reports are available "only with the grantee's approval". "Public Health Service Grants Policy Statement", *supra*, October 1, 1974, p. 57. Grantees should be entitled to rely on these policy statements as establishing the limits of the Government to the property of the project and while they may waive those limitations to allow basic data to be analyzed, they may also insist on freedom from disclosure. (Even if it were accepted that 45 C.F.R. § 74.24 provides a right of access to all records for all purposes, program as well as administrative, a right of access does not necessarily make a document the record of that

agency. It is still the record of the grantees at least until that right is exercised and control of the documents taken by the Government).

Unlike the regulations and policies dealing with grants, those dealing with contracts clearly vest in the Government the right to "use, duplicate or disclose all writings, recordings, charts, forms, data files and computer programs and any other records which are to be delivered under a contract". 41 C.F.R. § 3-16.950-315 (14) (the contract form for cost reimbursement contracts with educational institutions). The Department of Health, Education & Welfare could clearly make such data a deliverable product under a contract. Without an explicit provision to this effect in a grant award document or in grant regulations, a grant award would not give the Government such rights since grants are not intended to procure "deliverables" and are intended to assure the autonomy of the grantee and its investigators with respect to the management of the project. Where the Government intends to obtain basic research records as well as research effort and summary progress reports, a contract device must be used which specifies the basic research records as deliverables. Only in that way does the Government obtain a contractual right to treat such material as agency records.

3. Adverse Impact on Science of Requiring Disclosure

What impact would a decision in favor of the plaintiffs-petitioners have on the scientific research conducted with Federal funds in colleges and universities?

First, we must consider the meaning of the term "raw data". In the case before the Court, the raw data being

requested by the plaintiffs-petitioners are in the form of patient records, computer tapes and programs. However, if, in the future, raw data gathered with Federal funds were to be considered agency records under the Freedom of Information Act ("FOIA"), much of the data subsumed under that category would be recorded in the form of laboratory notebooks since there is no reasonable basis to distinguish under the FOIA that raw data from the raw data in this case. In the discussion that follows, we interpret the term raw data to include such laboratory notebooks. However, it should be observed that such raw data can come in many other forms, including field notebooks, strip charts, photographs, etc. Essentially, raw data includes all records of information, both basic and interpretive, related to the research project.

Laboratory notebooks are the basic records of the scientific activity of most investigators. In them are inscribed descriptions of experimental designs, figures from measurements they have made, questions that have occurred to them as the research proceeds, observations and other information and data. More than simple documents in which to record numbers, a scientist's notebooks are not unlike the sketchbooks of artists or composers, or an attorney's case files; they are the basic documents of their professional thinking that often encompass many of the scientist's creative reflections on research data. Personal in a way that the documents associated with an action taken by a Federal agency never can be, they are the intellectual diaries of scientists.

Normally, public or scientific interest in the data of a particular piece of research arises following the publication of the scientist's findings in a scientific journal

or the presentation of the findings before a professional meeting. Let us assume that the Government would not honor any requests for raw data under the Freedom of Information Act until after scientific investigators had made their findings public. At that stage, what impact would the release of their laboratory notebooks have?

At least three major problems are posed. First, laboratory notebooks commonly contain data that are not part of the published findings and that raise issues beyond the scope of the study that generated them. They include data the significance of which the scientist plans to explore at a later date when further research can be conducted to test or verify some hypotheses that the data suggest. If the notebooks were to be made available to anyone on request, this data would be released for others to interpret and use and would provide a serious disincentive to scientific exploration.

A second problem would be the misinterpretation that could result.

Research is a creative process, some of whose components are: the formulation of an hypothesis; the design of an experiment to test the hypothesis; the execution of the experiment, usually involving the collection of raw data; the comparison of the observed results with those predicted by the hypothesis; and, depending on whether or not the observed and predicted results were compatible, the making of a decision to seek further confirmation of the hypothesis or to revise it. This case focuses on only one element in this creative process—the collection of data—as though it were separable from the other essential and inter-connected parts. The public availability of raw

data, totally isolated from the context of the hypothesis under test and the experimental design, would more often than not lead to confusion, misunderstanding, or erroneous conclusions.

The third problem is that information in notebooks about the procedures used and circumstances under which the data were gathered is often skimpy. The scientist trusts his memory to fill the gaps. The requestor, lacking such knowledge, could be seriously misled by the insufficient notice of the information obtained. Also, the early data will usually not be derived from adequately controlled observations and will be very hard to interpret usefully. This too could result in egregious misinterpretation and error.

The problem of inadequate information could be solved by scientists deciding to keep their laboratory notebooks differently in the future. However, this solution would not solve the other problems mentioned. Scientific investigators can seldom forecast which of the data recorded in their notebook might turn out to be central or peripheral to their major conclusions. Inevitably, notebooks would sometimes contain clues of new scientific lodes to mine that are not germane to the Federally supported project and that they would rather not share with others.

There is also an issue regarding the scientist's professional privileges and credibility. These issues arise even more starkly if scientific investigators are required to release their notebooks before they have published findings. In the case before the Court, the request for the raw data was made after the results had been made public. Yet the interpretation of the FOIA being put forward by the plaintiffs does not restrict

the timing of the request. Nor does the FOIA itself do so. Therefore, unless the Court were to provide specific guidance on this issue, the result would stand that a request for raw data would have to be honored at any time after the raw data has come into existence. Thus, an issue arises as to premature release of research findings.

To consider the implications of the premature release of findings for the scientific community, we must understand the importance of the publication process through which most scientists make their findings public. The publication of the findings is an enormously significant benchmark for every scientist. Again there is a parallel with the legal system for advancing knowledge. A judge's words from the bench and his views as expressed in private conversation convey the direction of his legal thinking but the substance of his official position can only be conveyed in the language of his final opinion. The opinion is written and polished with that intent.

The same is true for scientists when they publish their findings. Scientific investigators and their peers view the process as essential for validation. Resolution of questions, criticisms and challenges articulated by peer referees during the process of securing the approval of the editorial board of the journal to publish a manuscript give weight and status to the final publication. The process has been described in this way in a major research journal: "The publication of scientific findings . . . involves refereed journals and thereby helps to ensure that those ideas which are published will not be applied before there has been adequate investigation and testing." T. Morgan, J. Keyes and J.

Sherman, *Confidentiality of Research Grant Protocols*, "Clinical Research", Vol. XXIV, No. 1, p. 10, 1976.

To allow a scientist's comments, findings and tentative interpretations, all of which are contained in his laboratory notebooks, to be released before the researcher feels ready to publish them formally is to rob him of the opportunity to live up to his own professional standards and to deprive him of his essential function of careful interpretation. Releasing the data and findings in this way destroys the traditional process of scientific discovery and seriously compromises and undermines the quality of the scientist's work.

Equally important, it diminishes the opportunity of the scientist to establish a sound professional reputation for himself and to advance his career. Imagining the worst possible circumstances, the scientist may find the contents of his laboratory notebooks about to be published under the authorship of another scientist. To thwart this plagiarism, the original observer may be forced into premature publication to establish priority for discovery, though compelled to do a less than professional job.

The preceding discussion has considered the effects that premature release of data and interpretations would have on the scientist and his reputation. Most important, however, is the fact that the premature release of data and findings serves the best interests of neither science nor the general public. This is for at least two reasons. First are the effects that the release can have on the scientists who conducted the research. In the most extreme case, they can be demoralized; in the best of worlds, discouraged and frustrated. Unable to set and meet their own professional standards,

stripped of their ability to make a reputation for themselves in their chosen field and of their ability to control their original idea, the investigators would be only human if they lost their strong desire to make further original contributions to research. Thus, the potential harm to the overall advancement of science is real.

Second, the premature release of data and findings confuses, distorts and often pollutes the scientific record. If raw data is released, inaccuracies and misinterpretations are sure to increase in number, with the likely result that science will advance more slowly than before and the emergence of truth will be delayed and error will thrive.

There is also the additional problem that premature release of data collected in clinical trials intended to establish the efficacy or safety of medical treatment may endanger the public. Early data in such trials may not accurately reflect the outcome of a major clinical trial because it will not reflect a large enough pool of information to be valid. The same can be said of large epidemiologic studies intended to establish the relationship between factors such as the environment, the use of food or drugs, age, or other circumstances, and disease. For a thorough discussion of this issue see Volume 44, *Federal Register*, No. 149, Wednesday, August 1, 1979 at page 45252, et seq. which contains a full notice of a meeting of the HEW Ethics Advisory Board involving consideration of proposals by the NIH and the Center for Disease Control of statutory amendments to protect such information from disclosure where it is information actually held by a Government agency.

4. Extent of Federally-Sponsored Research and the Impractical Aspects of a Decision in Support of Plaintiffs-Petitioners

In fiscal year ("FY") 1978, the Federal Government actually spent \$26 billion on research and development ("R&D") activity. "Special Analyses, Budget of the United States Government, Fiscal Year 1980", p. 295. The estimated obligations for fiscal year 1979 are \$29 billion. *Ibid.* In the current year, fiscal year 1979, about \$13 billion of the \$29 billion is accounted for by Defense Department R&D, \$4.6 billion by Department of Energy R&D, and \$3.7 billion by Department of Health, Education & Welfare R&D, principally the National Institutes of Health. *Ibid.* \$3 billion alone will be obligated by the National Institutes of Health for basic and applied biomedical research and related activity in FY 1979.

In FY 1978, health research generally was supported at a level of about \$4 billion with \$2.7 billion of that amount financed by the National Institutes of Health. "Basic Data Relating to the NIH", U.S. Department of Health, Education & Welfare, 1979, p. 3. Other agencies funding health research are the Veterans Administration, the Department of Defense, and the Alcoholism, Drug Abuse & Mental Health Administration of the Department of Health, Education & Welfare. *Ibid.* About 50%, or \$2 billion, of all health research and 58% of all National Institutes of Health research is carried out by higher educational institutions. *Id.*, at p. 3. Only 27% of all health research and 19% of National Institutes of Health research is actually performed by the Federal Government itself. *Ibid.* Clearly, the grant method of supporting research is the favored method by National Institutes of Health as

well as other R&D agencies since most of the support is in the form of grants.

Of the total \$2.7 billion National Institutes of Health funds expended for health research in fiscal year 1978, about \$2.1 billion was for research grants and contracts with the remainder for construction, research training and intramural research. "Basic Data Relating to the NIH", *supra*, p. 24. That \$2.1 billion produced 16,621 research grants and 2,026 contracts in fiscal year 1978. "Basic Data Relating to the NIH", *supra*, p. 24. The total number of research grants increased from 12,382 in fiscal year 1970 and 14,311 in fiscal year 1974 while research contracts have been about 2,000 in number since 1974. "Basic Data Relating to the NIH", *supra*, p. 24. A total of 374 higher educational institutions and 400 other non-profit institutions and their research staffs received awards in fiscal year 1978.

The extensive impact of a holding that raw research data in the possession of Federal grant recipients must be disclosed to the public is evident from these facts. Some 16,000 NIH research grants alone, each having a number of investigators, would be subject to this requirement. Obviously, research grantees of, for example, the Defense Department, the Department of Energy and the National Science Foundation could be subject to the same requirements involving time-consuming, inconvenient and possibly harmful disclosures.

Plaintiffs-Petitioners argue at page 25 of their brief that a judgment in their favor would have only limited impact on the vast array of Government sponsored research. They argue, in essence, that a decision in this case can be limited to its facts. However, there is little basis in the Freedom of Information Act, its legislative

history, or cases decided under it for the principles of limitation suggested by the plaintiffs-petitioners or by the facts which they allege to be unique. Plaintiffs-Petitioners contend that the research involved in this case is unique and non-replicable because the project was entirely funded by NIH, had substantial NIH involvement throughout, including a right of access to records authorized by NIH regulations, and involved Government reliance in a regulatory proceeding on the basic data involved. In his dissenting opinion in *Forsham v. Califano*, 587 F.2d 1128 (Circuit Court of Appeals for the D.C. Circuit, 1978) at p. 1142, Judge Bazelon adopts the position that where "federal funding of the data, federal access to the data and federal reliance on the data in an administrative proceeding" are all present as factors, the materials are agency records.

The first principle of limitation, that Federal funding is involved, does not distinguish this case from any of the 16,000 NIH research grants in existence in 1978. Even the extent of Federal funding offers little assistance here. First, no grant supported activity may by law be paid for entirely by grant funds. See Section 207 of H.R. 4389, the FY 1980 Appropriation Bill for the Department of Health, Education and Welfare, for an example of the traditional appropriations legislation requirement that grantees share in the cost of the supported undertaking. A similar provision has been a part of every annual Labor-HEW appropriation bill commencing with FY 1966. Thus, in addition to the equities of the grantee represented by the experience and creativity of the investigator and the research environment and support systems of the institution, the law creates additional equities in the grantee by assuring

that it bears some identifiable portion of the cost of the projects.

Since government funding will always be present in grant supported activity and will always be less than 100%, the petitioner's theory would require the Court to fashion some ratio of federal funds to grantee funds which would trigger the disclosure requirement. There being no statutory or legislative history to guide it, the Court would be required to choose between some precise but totally arbitrary threshold, such as 85% federal funds, and a less precise, conceptual threshold, such as a substantial or preponderant Federal contribution. The former would insert a new factor in the policies and considerations governing the extent of federal participation, essentially irrelevant to the mission of the agency and the significance of the research. The latter would leave both the government and the academic community in a sea of uncertainty. Greater precision would become a prerequisite of FOIA determinations and could only be achieved after exhausting and fruitless litigation.

With regard to a "substantial Federal involvement" principle of limitation, the record is similarly bereft of any guideposts suitable for constructing a threshold for disclosure. The question of what is substantial would thus be the subject of additional litigation until such a standard could be evolved. This is all the more unnecessary and regrettable in view of the statutory mandate that the contract be used as the instrument of support for activity substantially involving the government in its planning and execution. See 41 U.S.C. §§ 503 and 504. Furthermore, the contract mechanism has the additional advantage of facilitating the specification of the government's interest in the data, as re-

search contracts may, and often do, define the raw data as a product to be delivered. In such cases, what constitutes the agency record is ascertainable with a reasonable degree of certainty.

Furthermore, the alleged "right of access to grantee records" serves no useful function as a principle of limitation. While we in no way concur in the expansive reading of 45 C.F.R. § 74.24 advanced by the plaintiffs-petitioners, (see section 2 of this brief), the provision for audit access is equally applicable to all grant supported activity. Consequently, the petitioner's reading of this provision would serve no basis for limiting the scope of disclosure should they prevail in this case. On the contrary, all grantees would be equally susceptible to the demands for data disclosure.

Finally, it is claimed that in this case the Food & Drug Administration ("FDA") relied on the raw data in a regulatory proceeding and that therefore it became an agency record. To the extent that research data is involved in regulatory proceedings, parties with standing to participate in such proceedings have rights beyond those raised in this case under the Freedom of Information Act. See *Forsham v. Califano*, 587 F.2d 1128 (Circuit Court of Appeals for the D.C. Circuit, 1978), p. 1134. As Judge Leventhal noted, however, such regulatory proceedings and rights are not involved in this proceeding. As plaintiffs-petitioners note in their brief at page 51, their standing to participate in the FDA regulatory proceeding was limited. They should not be able to challenge that limitation in this proceeding which is what their claim attempts to do. Nonetheless, it seems clear from their brief at page 51 that they were able to raise the question of whether

this raw data was relied upon improperly or improperly omitted in the FDA proceeding.

Amici curiae suggest that the limited holding urged by plaintiffs-petitioners is not limiting for the reasons stated above. A holding for plaintiffs-petitioners will result in a principle of law that all raw data and records of research in projects supported primarily with Federal funds through the use of a grant agreement are agency records and subject to disclosure to any member of the public under the Freedom of Information Act. This is a Freedom of Information Act proceeding brought by members of the public, not a proceeding dealing with the adequacy or inadequacy of the record in a regulatory proceeding. None of the factors such as Federal funding, or unexercised rights of access under ordinary grant rules or other indicia of involvement of the Government distinguish this case for purposes of Freedom of Information Act law from any NIH research grant which produces raw data and records.

CONCLUSION

The extension of the concept of agency records under the Freedom of Information Act to raw data and basic scientific records of grantees of Federal research funds and the research investigators utilized by such grantees represents an unwarranted expansion of that Act which is inconsistent with Federal grant law and with the recognized Federal policy of stimulating investigator excellence through the autonomy a research grant permits. Such a decision would likely decrease the motivation of individual scientists supported by Federal grants and could well result in misleading and harmful release of incomplete or premature research data. We do not believe that Congress ever intended such a result nor that plaintiffs-petitioners desire it, but we see a holding for plaintiffs-petitioners having such consequences unless the decision is limited to facts unique to this case alone. However, as argued previously in this brief, we do not believe that there are facts relevant to this proceeding which distinguish this case from other NIH financed research which involves grant agreements.

Respectfully submitted,

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